

# HEPATITIS C: ACCESS, TESTING, AND TREATMENT IN THE VA HEALTH CARE SYSTEM

---

## HEARING

BEFORE THE  
SUBCOMMITTEE ON NATIONAL SECURITY,  
VETERANS AFFAIRS, AND INTERNATIONAL  
RELATIONS  
OF THE

COMMITTEE ON  
GOVERNMENT REFORM  
HOUSE OF REPRESENTATIVES  
ONE HUNDRED SIXTH CONGRESS

SECOND SESSION

JULY 12, 2000

**Serial No. 106-241**

Printed for the use of the Committee on Government Reform



Available via the World Wide Web: <http://www.gpo.gov/congress/house>  
<http://www.house.gov/reform>

U.S. GOVERNMENT PRINTING OFFICE

73-167 DTP

WASHINGTON : 2001

---

For sale by the Superintendent of Documents, U.S. Government Printing Office  
Internet: [bookstore.gpo.gov](http://bookstore.gpo.gov) Phone: (202) 512-1800 Fax: (202) 512-2250  
Mail: Stop SSOP, Washington, DC 20402-0001

## COMMITTEE ON GOVERNMENT REFORM

DAN BURTON, Indiana, *Chairman*

BENJAMIN A. GILMAN, New York	HENRY A. WAXMAN, California
CONSTANCE A. MORELLA, Maryland	TOM LANTOS, California
CHRISTOPHER SHAYS, Connecticut	ROBERT E. WISE, JR., West Virginia
ILEANA ROS-LEHTINEN, Florida	MAJOR R. OWENS, New York
JOHN M. McHUGH, New York	EDOLPHUS TOWNS, New York
STEPHEN HORN, California	PAUL E. KANJORSKI, Pennsylvania
JOHN L. MICA, Florida	PATSY T. MINK, Hawaii
THOMAS M. DAVIS, Virginia	CAROLYN B. MALONEY, New York
DAVID M. McINTOSH, Indiana	ELEANOR HOLMES NORTON, Washington,
MARK E. SOUDER, Indiana	DC
JOE SCARBOROUGH, Florida	CHAKA FATTAH, Pennsylvania
STEVEN C. LATOURETTE, Ohio	ELIJAH E. CUMMINGS, Maryland
MARSHALL "MARK" SANFORD, South	DENNIS J. KUCINICH, Ohio
Carolina	ROD R. BLAGOJEVICH, Illinois
BOB BARR, Georgia	DANNY K. DAVIS, Illinois
DAN MILLER, Florida	JOHN F. TIERNEY, Massachusetts
ASA HUTCHINSON, Arkansas	JIM TURNER, Texas
LEE TERRY, Nebraska	THOMAS H. ALLEN, Maine
JUDY BIGGERT, Illinois	HAROLD E. FORD, JR., Tennessee
GREG WALDEN, Oregon	JANICE D. SCHAKOWSKY, Illinois
DOUG OSE, California	-----
PAUL RYAN, Wisconsin	BERNARD SANDERS, Vermont
HELEN CHENOWETH-HAGE, Idaho	(Independent)
DAVID VITTER, Louisiana	

KEVIN BINGER, *Staff Director*

DANIEL R. MOLL, *Deputy Staff Director*

JAMES C. WILSON, *Chief Counsel*

ROBERT A. BRIGGS, *Clerk*

PHIL SCHILIRO, *Minority Staff Director*

## SUBCOMMITTEE ON NATIONAL SECURITY, VETERANS AFFAIRS, AND INTERNATIONAL RELATIONS

CHRISTOPHER SHAYS, Connecticut, *Chairman*

MARK E. SOUDER, Indiana	ROD R. BLAGOJEVICH, Illinois
ILEANA ROS-LEHTINEN, Florida	TOM LANTOS, California
JOHN M. McHUGH, New York	ROBERT E. WISE, JR., West Virginia
JOHN L. MICA, Florida	JOHN F. TIERNEY, Massachusetts
DAVID M. McINTOSH, Indiana	THOMAS H. ALLEN, Maine
MARSHALL "MARK" SANFORD, South	EDOLPHUS TOWNS, New York
Carolina	BERNARD SANDERS, Vermont
LEE TERRY, Nebraska	(Independent)
JUDY BIGGERT, Illinois	JANICE D. SCHAKOWSKY, Illinois
HELEN CHENOWETH-HAGE, Idaho	

## EX OFFICIO

DAN BURTON, Indiana	HENRY A. WAXMAN, California
LAWRENCE J. HALLORAN, <i>Staff Director and Counsel</i>	
KRISTINE McELROY, <i>Professional Staff Member</i>	
JASON CHUNG, <i>Clerk</i>	
DAVID RAPALLO, <i>Minority Counsel</i>	

## CONTENTS

---

Hearing held on July 12, 2000 .....	Page 1
Statement of:	
Baker, Terry, executive director, Veterans Aimed Towards Awareness, Inc. ....	16
Brau, Dr. Norbert, M.D., staff physician, Bronx VA Medical Center .....	83
Bryant, James A., Vietnam veteran .....	24, 27
French, Heather, Miss America 2000 .....	5
Ho, Dr. Samuel B., M.D., staff physician, Minneapolis VA Medical Center .....	72
Holohan, Dr. Thomas V., M.D., Chief, Patient Care Services Officer, Veterans Health Administration, accompanied by Jimmy Norris, Chief Financial Officer, Veterans Health Administration .....	51
Iber, Dr. Frank, M.D., hepatologist, volunteer at Hines VA Medical Center, Hines, IL .....	88
Lesinski, Martin P., Vietnam veteran .....	37
Letters, statements, etc., submitted for the record by:	
Baker, Terry, executive director, Veterans Aimed Towards Awareness, Inc., prepared statement of .....	19
Brau, Dr. Norbert, M.D., staff physician, Bronx VA Medical Center, prepared statement of .....	86
Bryant, James A., Vietnam veteran, prepared statement of .....	30
French, Heather, Miss America 2000, prepared statement of .....	9
Ho, Dr. Samuel B., M.D., staff physician, Minneapolis VA Medical Center, prepared statement of .....	75
Holohan, Dr. Thomas V., M.D., Chief, Patient Care Services Officer, Veterans Health Administration, prepared statement of .....	54
Iber, Dr. Frank, M.D., hepatologist, volunteer at Hines VA Medical Center, Hines, IL, prepared statement of .....	90
Lesinski, Martin P., Vietnam veteran, prepared statement of .....	40
Shays, Hon. Christopher, a Representative in Congress from the State of Connecticut, prepared statement of .....	3



## HEPATITIS C: ACCESS, TESTING, AND TREATMENT IN THE VA HEALTH CARE SYSTEM

WEDNESDAY, JULY 12, 2000

HOUSE OF REPRESENTATIVES,  
SUBCOMMITTEE ON NATIONAL SECURITY, VETERANS  
AFFAIRS, AND INTERNATIONAL RELATIONS,  
COMMITTEE ON GOVERNMENT REFORM,  
*Washington, DC.*

The subcommittee met, pursuant to notice, at 10:06 a.m., in room 2154, Rayburn House Office Building, Hon. Christopher Shays (chairman of the subcommittee) presiding.

Present: Representatives Shays, Souder, Tierney, and Allen.

Also present: Representative Snyder.

Staff present: Lawrence J. Halloran, staff director and counsel; Robert Newman and Kristine McElroy, professional staff members; Jason M. Chung, clerk; David Rapallo, minority counsel; and Ellen Rayner, minority clerk.

Mr. SHAYS. The hearing will come to order.

I would like to welcome our witnesses and our guests.

In confronting the epidemic of hepatitis C virus [HCV] infection, which afflicts veterans five to six times more often than the general population, the Department of Veterans Affairs [VA] is leading other public health systems in the development of screening, diagnostic, and treatment protocols. But since the program announcement 18 months ago, we have begun to question whether the VA health care system is capable of carrying out those protocols and delivering on the promise to conduct a sustained campaign against the silent killer.

Time is running out. A potentially fatal biological clock is ticking down for many thousands infected by HCV-tainted blood and blood products during the 1970's and 1980's. Unless they are told they are at risk, tested, and appropriately treated, many will suffer liver damage beyond the reach of current medical therapies.

VA acknowledges the potential scope and genuine urgency of the problem, with 18 to 20 percent of veterans testing positive for HCV antibodies. Yet veterans' advocates report inordinately long waits for appointments with liver specialists and inconsistent approaches to HCV care between VA regions. The percentage of HCV-positive veterans enrolled in the only effectively, but costly, drug treatment is well below some VA projections of just a year ago. The scarcity of qualified specialists and the rigid criteria used to exclude so many from treatment in some areas raise legitimate questions whether VA medical network directors are being given the organi-

zational and budgetary support needed to drive this ambitious program.

Recently, VA addressed the apparent fiscal disincentives to aggressive hepatitis C outreach by allocating \$20 million in reserve funding to the networks based on HCV-related expenses this year. More permanent incentives will be included in regional funding formulas for next year.

This is our third oversight hearing on the VA's hepatitis C program. Last year, witnesses described the fiscal and operational challenges posed by the still new-born program. Last June, testimony described growing pains, but progress in contacting veterans, standardizing care, and making treatments more available.

But today the question remains whether a consistent, effective, and truly national hepatitis C program is being constructed across the decentralized VA health care system. How can a sometimes resistant, sluggish bureaucracy adapt to the unique, changing demands for HCV treatment? These are the critical questions we are asking our witnesses to address this morning.

Speaking for veterans affected by hepatitis C, our first panel is graced by the presence of the reigning Miss America, Miss Heather French. She has made it a central element of her public life to advocate on behalf of homeless veterans. We thank her for all she does to heighten public awareness of veterans' needs, and we are grateful she is able to join us today.

All our witnesses bring important perspectives and experiences to our discussion of the VA hepatitis C initiative, and we look forward to their testimony as well.

[The prepared statement of Hon. Christopher Shays follows:]

CAN BURTON, INDIANA  
C-ARMAN

BENJAMIN A. DILMAN, NEW YORK  
CONSTANCE A. MADRELLA, MARYLAND  
CHRISTOPHER SHAYS, CONNECTICUT  
LEANA JOSELENTHEIN, FLORIDA  
JOHN V. MCARDLE, NEW YORK  
STEPHEN YORRI, CALIFORNIA  
JOHN L. WICK, FLORIDA  
THOMAS W. DAVIS II, VIRGINIA  
TIM MCINTOSH, INDIANA  
E. SLODER, INDIANA  
JACK BORDOWITZ, FLORIDA  
STEVEN C. LAFOURETTE, OHIO  
MARSHALL MARK GANFORD, SOUTH CAROLINA  
BOB BARR, GEORGIA  
DAN VILLER, FLORIDA  
ASA M. CHINSON, ARKANSAS  
LEE TERRY, NEBRASKA  
JUDY SUGERT, ILLINOIS  
GREG WALDEN, OREGON  
DOUG OBE, CALIFORNIA  
PAUL RYAN, WISCONSIN  
HELEN CHENOWETH HAGE, IDAHO  
DAVID HITTER, LOUISIANA

ONE HUNDRED SIXTH CONGRESS

## Congress of the United States House of Representatives

COMMITTEE ON GOVERNMENT REFORM

2157 RAYBURN HOUSE OFFICE BUILDING

WASHINGTON, DC 20515-6143

MALETTY (202) 225-5074  
MALETTY (202) 225-5051  
TTY (202) 225-6832

SUBCOMMITTEE ON NATIONAL SECURITY, VETERANS AFFAIRS  
AND INTERNATIONAL RELATIONS

Christopher Shays, Connecticut  
Chairman

Room B-372 Rayburn Building

Washington, D.C. 20515

Tel: 202 225-2548

Fax: 202 225-2382

E-mail: nevair.groc@mail.house.gov

HENRY A. WALZMAN, CALIFORNIA  
RANKING MINORITY MEMBER

TOM LANTOS, CALIFORNIA  
ROBERT E. WISE, JR., WEST VIRGINIA  
MAJORIE OWENS, NEW YORK  
EDOLPHUS TOWNS, NEW YORK  
PAUL E. KANDERSO, PENNSYLVANIA  
PATSY T. WALK, HAWAII  
CAROLYN B. MALONEY, NEW YORK  
ELEANOR HOLMES NORTON,  
DISTRICT OF COLUMBIA  
CHAKA FATTAH, PENNSYLVANIA  
ELUANE CUMMINGS, MARYLAND  
DENNIS J. KUCIUCH, OHIO  
ROD R. BLAGUESKY, ILLINOIS  
DANIEL K. DAVIS, ILLINOIS  
JOHN P. TIERNEY, MASSACHUSETTS  
JIM TURNER, TEXAS  
THOMAS W. ALLEN, MAINE  
HAROLD E. FORD, JR., TENNESSEE  
JANICE D. SCHAKOWSKY, ILLINOIS

BERNARD SANDERS, VERMONT  
HIDEPOGAT

### Statement of Rep. Christopher Shays July 12, 2000

In confronting the epidemic of hepatitis C virus (HCV) infection, which afflicts veterans five to six times more often than the general population, the Department of Veterans Affairs (VA) is leading other public health systems in the development of screening, diagnostic and treatment protocols. But since the program announcement eighteen months ago, we have begun to question whether the VA health care system is capable of carrying out those protocols and delivering on the promise to conduct a sustained campaign against the silent killer.

Time is running out. A potentially fatal biological clock is ticking down for many thousands infected by HCV-tainted blood and blood products during the 1970s and 1980s. Unless they are told they are at risk, tested and appropriately treated, many will suffer liver damage beyond the reach of current medical therapies.

VA acknowledges the potential scope and genuine urgency of the problem, with 18 to 20 percent of veterans testing positive for HCV antibodies. Yet veterans' advocates report inordinately long waits for appointments with liver specialists and inconsistent approaches to HCV care between VA regions. The percentage of HCV-positive veterans enrolled in the only effective, but costly, drug treatment is well below some VA projections of just a year ago. The scarcity of qualified specialists, and the rigid criteria used to exclude so many from treatment in some areas, raise legitimate questions whether VA medical network directors are being given the organizational and budgetary support needed to drive this ambitious program.

Recently, VA addressed the apparent fiscal disincentives to aggressive hepatitis C outreach by allocating twenty million dollars in reserve funding to the networks based on HCV-related expenses this year. More permanent incentives will be included in regional funding formulas for next year.

Statement of Rep. Christopher Shays  
July 12, 2000  
Page 2

This is our third oversight hearing on the VA's hepatitis C program. Last year, witnesses described the fiscal and operational challenges posed by the still-new program. Last June, testimony described growing pains, but progress in contacting veterans, standardizing care and making treatments more available.

But today the question remains whether a consistent, effective and truly national hepatitis C program is being constructed across the decentralized VA health care system. How can a sometimes resistant, sluggish bureaucracy adapt to the unique, changing demands for HCV treatment? These are the central questions we asked our witnesses to address this morning.

Speaking for veterans affected by hepatitis C, our first panel is graced by the presence of the reigning Miss America, Ms. Heather French. She has made it a central element of her public life to advocate on behalf of homeless veterans. We thank her for all she does to heighten public awareness of veterans' needs, and we are grateful she is able to join us today.

All our witnesses bring important perspectives and experiences to our discussion of the VA's hepatitis C initiative, and we look forward to their testimony.



Mr. SHAYS. Let me now turn to the ranking member of the committee, Mr. Tierney, if he would like to make any statement.

Mr. TIERNEY. I have no opening statement, Mr. Chairman, but I will defer to either one of my colleagues if they would care to say something.

Mr. SHAYS. Mr. Allen.

Mr. ALLEN. Very briefly, Mr. Chairman. I just would say I thank you for holding this hearing. I think those of us, no matter where we live in this country and whom we represent, we are dealing with a struggle that so many of our veterans, particularly of the Vietnam era, are homeless and have a variety of disabilities and a variety of problems that go along with that. I think this hearing is an important one today, and I simply want to say thank you for holding it.

Mr. SHAYS. I thank the gentleman.

We are also privileged to have Vic Snyder from Arkansas, who serves on the Armed Services Committee and also on the Veterans Committee, I think on the subcommittee on health. It is nice to have you here as well. Welcome. If you would like to make any comment?

Mr. SNYDER. No, thank you.

Mr. SHAYS. As is our custom and practice, we swear in all our witnesses. I would welcome you all to stand and we will swear you in.

Raise your right hands, please.

[Witnesses sworn.]

Mr. SHAYS. For the record, all of our witnesses have responded in the affirmative.

And if I could, just to get some housekeeping out of the way and then we will recognize you, Miss French. I ask unanimous consent that all members of the subcommittee be permitted to place an opening statement in the record and that the record remain open for 3 days for that purpose. Without objection, so ordered.

I ask further unanimous consent that all witnesses be permitted to include their written statement in the record. Without objection, so ordered.

Miss French, I know you have an extraordinarily busy schedule and that you will need to leave here in about a half an hour. We are going to have you give your testimony. I think we will be able to have Mr. Baker, Mr. Bryant, and Mr. Lesinski give their testimony, it will be within 5 minutes I think, and then we will proceed to ask you a question or two. And if we are not able to get through the testimony, we will interrupt and make sure that we have some questions for you. Welcome. Great to have you.

#### **STATEMENT OF HEATHER FRENCH, MISS AMERICA 2000**

Miss FRENCH. Chairman Shays and members of the subcommittee, I thank you from the bottom of my heart for allowing me to be here to represent millions of our American veterans, especially those who are continuing to fight for their health, fighting to regain their health. For so many, as you know, the war continues on. It did not end when they came home.

As Miss America 2000, I have been able to travel this country with a great trophy—not a trophy that since September 18 belongs

to me, but a trophy that belongs to 25 million American veterans. I have carried this crown around the country with me to represent every veteran. Every stone, every sparkle, it is their trophy, not mine. I know a lot of you today ask yourselves why does a 25 year-old fashion designer who has become Miss America care about veterans' issues. I will tell you why.

First and foremost, beyond being Miss America, I am the very proud daughter of a disabled Vietnam veteran. At the age of 4 my father started taking me into the VA hospital with him to receive treatment. At that time, there was a very long waiting period for his treatments. But it was at that time that I learned the greatest lesson of responsibility concerning our veterans. And that is, where veterans are concerned, it is so much better to listen, not just with your ears but with your heart, because it does not just make a difference in how you treat our veterans, it makes the difference in how we respect their service.

Then growing up, as a young adult I started running for Miss America and realized that the spotlight for Miss America could spread a spotlight on issues that this country did not know about. We could expose issues that our veterans needed to have exposed. We could gain them a better present and, more importantly, a better future.

This year I have recorded about 20,000 miles each month, 1 day off a month, and have been able to see the different faces of the Nation where veterans' issues are concerned. I have travelled State to State. I have been able to embark upon many wonderful issues this year. One of those not just being homelessness among veterans, but because of Vietnam Veterans of America and Veterans Aimed Toward Awareness, I have now embarked upon a tour fighting the silent enemy hepatitis C.

At one of the screenings that we have done together this year, almost 30 percent of the veterans at a particular event were diagnosed positive for hepatitis C. I do not think I need to tell you that 4 million Americans today are infected with hepatitis C. And as Chairman Shays said earlier, veterans are five, six times more likely to receive hepatitis C because of their one common denominator, and that would be their service to our country.

It has come to my attention that many of our veterans are scared to get tested. Many do not know how they could have been infected. But what we want to see is a more consistent approach to hepatitis C across the country. My father has told me countless stories of carrying his friends' bodies off the battlefield, being drenched in blood for days. Of course, we have to look at a very high risk factor of blood transfusions. Two years alone in Vietnam there were over 365,000 blood transfusions. And what about the helicopter pilots, the medics, the nurses, the surgeons who were over there as well. And I do not think I even have to express my opinion about the 5 to 8 percent of those in the Vietnam population who are hepatitis C positive.

We sent 2 million of our soldiers, we deployed them to Vietnam, into combat, they were unprotected from hepatitis C. Therefore, I do not think it is a coincidence that almost 10 percent of our American veterans are infected with hepatitis C. I believe that one com-

mon denominator comes down, again, to their service to this country.

There is an effective treatment we have been able to tell millions of veterans across the country who have gotten screened. However, we do not believe that treatment is consistent across the country. Some of the veterans I have talked to have expressed their concern of not being able to receive treatment, getting screened, or getting tested. My question is, why?

I understand that we have a very decentralized VA system. I understand that the veterans in Louisville, KY are not the same as the veterans in New York City. However, a veteran who has hepatitis C in Louisville, KY is the same as a veteran who has hepatitis C in New York City. I am interested in why even the Centers of Excellence in our country do not have the funding or the staff to meet the needs of the veterans that are coming in their doors.

I have visited the Miami Medical Center. They are a Center of Excellence. Yet, it was expressed to me that they received less than \$300,000 last year for hepatitis C treatment. I have been to the New York Harbor Side Health Care System. They are a Center of Excellence for hepatitis C. Their hepatitis C team expressed to me that they had to use their vacation time, their lunch time, their breaks in order to meet the needs of their current hepatitis C-positive population. My question is what happens in a year or two when 2,000 more hepatitis C-positive patients come to them for treatment. What happens then?

So again we ask you to look at the VA health system. We need to implement a plan that is consistent across the board from all VA perspectives, throughout all regions, because our veterans in this United States deserve that much. They deserve the chance to walk into a VA and be welcomed. When a dear friend of mine, Butch Silvey came to me in Augusta, KY, a disabled Vietnam veteran, during my homecoming he handed me a present that reminds me every single day why I fight and the price that he paid. This gentleman was sent to Vietnam, was shot not once, not twice, but three times. He received this Purple Heart. He gave this to me to remember why I fight every day. This is the price that has been paid.

Everyday our veterans are being left behind. They are not being treated, not being screened, not being respected for their service. My question again, how many have to suffer, how many have to die before we wake up and take notice? This is our responsibility to this Nation.

Also, it is our responsibility to set the stage for our coming generations, our children. I understand that 1 day we will wake up and the voice we had will have been passed on to our children. So what type of legacy are we leaving for our children. Are we leaving a legacy of responsibility, of accountability? Do they know how to take care of our veterans? I think the mistreatment of thousands of hepatitis C-positive veterans would say otherwise. It tells a whole different story.

So today it is your choice to make that stand. It is your choice to face the wind. We need to be a hero to these veterans. We need to be a hero to our children, because I believe the American people are looking for those who dare to talk the talk and walk the walk.

I think a lot of veterans in this room will agree with me that we are long tired of the patronizing speeches of Veteran's Day, those who patronize our veterans 1 day, leave them in a waiting line the next. It is time to live up to that promise.

I encourage you, as you listen to my remarks, as you take them to ponder on, remember this one thing: The choices you make today reflect upon the American society. Their character is a reflection of you. You make their choices for them. So I ask that you please be wise, be compassionate where veterans are concerned because the decisions you make will depict how our veterans are proud of their service. I would ask you that you make the decisions that let them be proud to be American veterans. Thank you.

[Applause.]

[The prepared statement of Miss French follows:]



HELPING VETERANS FIGHT A SILENT ENEMY — HEPATITIS C

**STATEMENT OF**

**Heather French**

**Miss America**

**COMMITTEE ON GOVERNMENT REFORM**

**SUBCOMMITTEE ON NATIONAL SECURITY, VETERANS AFFAIRS  
AND INTERNATIONAL RELATIONS**

**HEPATITIS C:  
ACCESS, TESTING and TREATMENT  
IN THE VA HEALTH CARE SYSTEM**

**JULY 12, 2000**

Chairman Shays and Members of the Subcommittee, I am pleased to be here this morning to speak on behalf of millions of American veterans who have fought for our country. Veterans who are now fighting to regain their health. For so many, the wars are not over.

As the daughter of a disabled Vietnam veteran, I have had the opportunity to learn some important lessons about the trauma, illness and injury many veterans experienced during their service to our great country and continue to experience long after returning home to their families. In listening and talking to veterans at VA hospitals, I have grown to respect the lifelong sacrifices our veterans made when they stepped forward to defend this nation.

When I became Miss America 2000, the twenty-seven million veterans in America gained a dedicated advocate. I have made it my priority to be a voice for veterans and to put the spotlight on their concerns and issues. It is time, in the new millennium, to bring the veterans home with us. To look at their present conditions and lead them into the future. And part of this is taking care of hidden issues. Issues that our country likes to put into the background; issues we tend to blame on something other than the veteran's service to his country.

Hepatitis C is one of these issues. Here is a disease that affects more than one in ten veterans. Many are Vietnam veterans who have carried the virus for twenty-five years, or longer, and are now dying from related liver disease. Twenty to thirty percent of all liver transplants conducted in the United States today are due to hepatitis C. Veterans in VA hospitals across the country are waiting for transplants because their livers have been destroyed by this disease -- a disease many contracted during their service.

Current estimates indicate that about 4 million Americans are infected with the hepatitis C virus. This year alone 8,000 to 10,000 Americans will die from it. Most will be veterans since they are five to six times more likely to have the disease than the general public. This is an example of how war goes on and on, and how veterans continue to fight and die.

None of us want our country's veterans to suffer, particularly not from preventable and treatable diseases such as hepatitis C. As Miss America, I began my national speaking tour honoring our nation's homeless veterans. But I quickly found myself a multifaceted veteran's advocate. Not just working for homeless veterans but working for all veterans, because the concerns that face homeless veterans face all veterans. Health benefits, disability, lack of jobs.

When I realized that so many veterans were infected with hepatitis C, and that too many were not getting the treatment they need to overcome the disease, I decided to join the Vietnam Veterans of America and the Veterans Aimed Toward Awareness and help conduct a national disease awareness campaign called "Helping Veterans Fight A Silent Enemy: Hepatitis C."

Hepatitis C is called the silent enemy because it does not cause obvious symptoms until ten to thirty years after infection. Many people have end-stage liver disease caused by the virus by the time they learn that they are infected. Through stored blood samples taken from military soldiers in 1948, scientists have been able to determine that hepatitis C has existed in the military community for at least fifty years. But the virus was not isolated until 1989 and there was not a reliable test to detect it in blood until 1992.

It is not a coincidence that approximately ten percent of veterans are infected with hepatitis C. We know that before 1992 -- when the first reliable blood test for hepatitis C became available -- the virus was a significant threat to combat veterans who received blood transfusions after suffering battlefield wounds. Because hepatitis C is transmitted through blood to blood contact, all veterans who received blood transfusions, underwent hemodialysis, worked as medics, or experienced combat were put at high risk for contracting the virus. My father has talked about the tragedies he and fellow soldiers faced during Vietnam. He has talked about days where they walked through the bush soaked in their brothers' and sisters' blood. Veterans are the highest-risk population for hepatitis C because of the exposure they experienced serving our country.

Studies conducted by the Washington and San Francisco VA medical centers have found rates of hepatitis C among inpatients to be 20% and 23%, respectively. Estimates of the rate of infection among Vietnam veterans (in and out of the VA system) range from 18.9% to 27.3%. Of all the military veteran populations tested throughout VA medical facilities nationwide, Vietnam-era veterans accounted for about 64% of all positive hepatitis C tests.

Given the long latency period for this disease, many soldiers exposed to the virus in Vietnam are just starting to see the signs of advanced liver disease. Estimates from the VA health system indicate that incidence of liver disease related to hepatitis C will continue to increase at a rapid rate as the Vietnam population infected with the virus begins to show symptoms of disease.

Vietnam-era veterans have unusually high rates of hepatitis C infection for several reasons. For one, tainted blood transfusions and blood products were responsible for a substantial portion of hepatitis C transmissions before 1992; and use of blood transfusions for treatment of combat-related injuries was commonplace during the Vietnam war. Approximately 365,000 blood transfusions were performed among United States personnel in Vietnam between 1967 and 1969 alone. Researchers aware of the phenomenon of "post-transfusion hepatitis" in the early 1970s estimated that 20% of blood supplies in that period were infected with "non-A, non-B hepatitis" (now determined to be largely hepatitis C).

At the same time, blood supplies shipped to Vietnam in the late 1960s and early 1970s may have been infected at a higher rate because some of the blood used was from paid donors. Also, a large proportion of the whole blood transfused to American soldiers during the Vietnam War may have been obtained from Southeast Asia, where hepatitis C rates were already high. Today, between 5% and 8% of the Vietnam population is infected with hepatitis C, compared to 1.8% of the U.S. population.

Another major factor affecting hepatitis C infection in Vietnam was medical contact. Surgeons, nurses, medics, helicopter crews, and others involved in evacuation and treatment of the wounded all were at risk for transmission of hepatitis C. And an estimated 41.1% of all soldiers deployed to Vietnam -- approximately 2.1 million --- were exposed to combat, and consequently hepatitis C. Many soldiers assisted the more than 300,000 wounded.

In addition to transmission through blood transfusion and medical contact, hepatitis C could have been transmitted to military personnel through tattoos, sexual contact and IV drug use, although these means of transmission are far less likely for this population. Although sexual transmission of hepatitis C is possible, studies to date have shown only low rates of sexual transmission and it is believed to be relatively uncommon. While transmission through IV drug use is far more established, this kind of drug use appears to have been fairly limited in Vietnam. A Centers for Disease Control and Prevention study of the health status of Vietnam veterans found that only 3% had used "hard drugs" defined to include amphetamines, barbiturates, cocaine, heroin, psychedelics, phencyclidine and methaqualone.

It is also very important to point out that we do not know all the risk factors for transmission of hepatitis C. About twenty percent of infections are unexplained by available science. Veterans who were not exposed to clear risk factors -- such as blood transfusions or combat -- often express frustration about how they got the



virus. This issue of transmission should be further studied, but in the meantime, veterans with infections should be treated whenever possible.

If treatment of this virus is not accelerated, there will be a rapid increase in liver disease and liver transplants among our veterans. Liver transplant shortage due to hepatitis C is already a serious problem. Researchers predict that by 2008 current cases of chronic hepatitis C will result in a 528% increase in the need for liver transplants and a 223% increase in liver-related deaths. There is effective treatment for this virus, but only a small percentage of people with the disease are being treated.

The current standard treatment for hepatitis C is a combination of interferon and ribavirin. The treatment is similar to the antiviral cocktail used to treat patients with HIV. It can be difficult to take because of side effects, which can include fatigue, shortness of breath, mental confusion, depression and other things. Consequently, the VA must do more than provide funding for hepatitis C treatment. The department needs to set up a system that provides hepatitis C clinics in all VA facilities so that veterans can get treatment close to home. These clinics should be staffed with knowledgeable personnel that veterans can reach to talk about treatment complications and concerns. Helping veterans through the treatment is an important part of the battle that the VA must undertake to help fight this disease.

Expediting treatment will save lives and money. Experts say medical costs for patients whose disease progresses to include cirrhosis and/or advanced liver disease can be dozens to hundreds of times higher than the average per-capita medical costs in the United States. On the other hand, experts predict that curative treatment will pay for itself within about ten years, even before calculating the cost savings associated with avoiding disability and lost work days.

During my work with the veterans organizations I've learned that there are significant problems with the screening, testing and treatment approaches taken at the various VA medical facilities across the country. In some areas, veterans with hepatitis C are simply not getting screened, tested or treated. The VA needs to implement a consistent hepatitis C treatment approach at medical facilities across the country, not just in a handful of hospitals located in major metropolitan areas.

In January 1999 the VA announced a Veteran's health initiative to detect hepatitis C in the VA population and increase testing and treatment where appropriate. The department promised that every patient who needs and desires treatment for

hepatitis C would received it. But, to date, the department's initiative has experienced varying degrees of success. Due to the VA's decentralized management system (known as the VISN system, where the VA's medical facilities and offices are divided geographically into 22 regional networks), even the VA Central Office's best-intended plans are not implemented uniformly by the VISNs or local hospitals.

Many VA hospitals currently have waiting periods of four to six weeks before a veteran is able to see a gastrointestinal physician for hepatitis C. Many VA hospitals do not have the adequate staff to manage the increase in hepatitis C patients and most hospitals have yet to create any kind of outreach program to help veterans and their families cope with this disease. Although the VA announced its initiative almost two years ago, it has not yet developed the additional infrastructure needed to meet the needs of veterans with hepatitis C.

It is time we took care of our veterans.

It is critical that this subcommittee and VA officials implement a consistent and effective hepatitis C treatment approach at medical facilities across the country. It is also important that the subcommittee and VA officials reconsider treatment guidelines that call for therapy only after a patients' liver is in distress and his or her overall health is in jeopardy. Why not provide treatment to veterans we know are infected before they become symptomatic? Before they progress to advanced liver disease? Before their lives are turned upside down by this debilitating disease? Experts say relatively healthy patients have fewer problems with treatment. So why are we waiting to treat infected veterans?

Many veterans with hepatitis C say that the disease causes mental confusion and severe fatigue that makes fighting for treatment rights and disability benefits all the more difficult. Some say they just do not have the energy to jump through any more bureaucratic hoops. Some have simply lost hope. Since September, when I was crowned Miss America, I have logged thousands of miles traveling our country to speak about hepatitis C. Yet, I have not grown tired of speaking for our veterans and their families because this issue is so important. I want to point out that it is important to remember the families because of the potential for household transmission of hepatitis C. The families that support veterans should also be aware of their risk for infection. We need to do more to make sure that screening, testing and treatment are available to them as well.

When I was growing up dealing with my father's disabilities, it took our whole family working together to pull through the difficult times. Without my mom helping my father, without my brothers and sisters helping me get through my father's disabilities, my family would not be connected together today. The families of veterans understand the price of freedom. When we honor our veterans and their families and give them the care they need, we also honor the communities in which we live.

We can give veterans with hepatitis C and their families hope by making it easier for them to get the treatment they need, when they need it. Chairman Shays and members of the subcommittee, thank you for holding this important hearing and working to give our nation's veterans and their families the care they are due.

Mr. SHAYS. Thank you, Miss French.  
Mr. Baker.

**STATEMENT OF TERRY BAKER, EXECUTIVE DIRECTOR,  
VETERANS AIMED TOWARDS AWARENESS, INC.**

Mr. BAKER. Dear Mr. Chairman and other distinguished guests of the subcommittee, on behalf of Veterans Aimed Toward Awareness [VATA], a support group for veterans with hepatitis C, and Vietnam Veterans of America Chapter 83, I am honored to be here a second time regarding the VA's handling of the hepatitis C epidemic.

Since June 9, 1999, when we last met, I have been traveling around the country talking to veterans, offering them hepatitis C testing and counseling, visiting VA hospitals and clinics, and corresponding with Dr. Garthwaite and his counterparts. I have attended one of the VA's training symposiums on hepatitis C and visited the Miami Hepatitis C Center of Excellence.

Members of the committee, other than the efforts of my organization to provide education, counseling, and testing, I have not seen the proactive or aggressive efforts on the part of the VA which they promised this committee on June 9, 1999.

Talking with veterans, I have found that the VA's approach to treatment is only to treat those veterans who have high liver enzyme levels, those who have symptomatic liver disease, and those who are possibly beyond help, instead of treating the veterans who could benefit most from the dual therapy. In my view, the VA is treating the veterans who will benefit the least.

In fact, in a letter to this committee dated June 28, 2000, Dr. Garthwaite seemed proud of the fact that 78 percent of veterans receiving treatment within the VA are designated into the "complex care" category. I believe that Dr. Garthwaite intended to impress upon you and this committee that HCV cases are being properly reimbursed to the medical centers. In fact, 78 percent of all veterans being treated fall into the complex care category because the VAMCs are treating only those veterans who are sick enough to meet the strict criteria of being a complex care patient in the VA.

Furthermore, it is my humble opinion that most treatment is being reserved for complex care patients because VAMCs realize that they cannot afford to start basic care patient on the expensive therapy because they only generate \$4,000 per patient per year. They are well aware that the estimated VA HCV patient needs care with an average cost to the VA of between \$25,000 and \$40,000. To treat HCV patients who fall into the basic care category would bankrupt the particular hospital delivering the care. The VA medical centers must wait for their HCV patients to progress to more serious complications, like ascites, in order for the medical records of the patients to note the appropriate diagnostic codes to allow the VA medical center to collect the complex care funding.

One of the only VISNs that treats the virus as the sole enemy is VISN 13, under the supervision of Dr. Sam Ho. If VA ever designates another Center of Excellence in hepatitis C care, it should be Dr. Ho's. He and Dr. Petzel treat veterans with real respect and

see HCV as a disease that can and should be eradicated from every veteran, no questions asked.

Following last year's hearing, we approached Dr. Garthwaite about assisting the individual VISNs with their HCV programs and helping them improve particular HCV-related shortcomings witnessed in various VISNs. He told us to direct our concerns to the individual VISNs, which we did by letters to each VISN this past March. To our surprise, instead of working with the particular VISNs on HCV, as originally instructed by Dr. Garthwaite, we received one letter from VA central office on behalf of all 21 VISNs. So much for a decentralized system.

Concerning all the correspondence that we have had with central office, it certainly seems to me that someone is trying to placate me. Because there are more important matters to discuss, and there is little time now, I have brought these letters and correspondence so that you can review them at a later date.

I have been asked to followup on the examples that I produced last year. Mr. Chairman, I am sorry to report that these veterans' lives have gotten dramatically worse. The veteran from Idaho was finally tested, but has not yet been allowed to receive treatment in VISN 19. In fact, he has been told that despite evidence of fibrosis of the liver, his enzyme levels are not elevated enough to consider him for treatment. As for the veteran from Montana, the VA has done a fine job. He was never treated for his hepatitis C, and in November of last year he succumbed to complications from a liver transplant due to hepatitis C. I attended his funeral.

In the case of my personal friend from New Jersey that served with the 173rd Airborne, he is now No. 7 on the liver transplant waiting list. Even though we personally delivered his case to Dr. Garthwaite, no, I repeat no action has been taken. The VA continues to maintain that this recipient of the Bronze Star for Valor cannot show a nexus between his service and his hepatitis C infection because his duty assignment was not "medic." So much for serving one's country and believing that one's country will bind up the wounds of battle.

Committee members, I must stress that while the VA tells us that they are doing all that they can, the veterans caught in the middle of this war do not have the time for the VA to continually drag their feet. I have personally, along with some fine people, brought forth more awareness from my little office than all of the VA.

I find it appalling and take great umbrage at the duplicitous nature of the VA's central office. There are solutions to these problems, and I think that if a simple, long-haired country boy like me can figure them out, so can these highly educated people. Simple things, like letting infectious disease physicians actively assist in providing treatment for this disease. If the VA has a shortage of gastroenterologists, then let us use the currently under-utilized infrastructure that was built within the VA to provide treatment for AIDS. Let us use them to treat HCV. After all, the therapy is very similar and HCV is an infectious disease. If we still do not have enough manpower, let us look at flexible hiring schemes.

Another important point to consider is that the VA should really be one VA when it comes to this disease. For example, a veteran

from Montana should not have to relocate to Phoenix to get treatment. For more suggestions, I will be glad to meet with the committee and the VA to develop a more productive program for our hepatitis C patients. In fact, I would like to volunteer to serve on the Advisory Committee that the VA Office of the Inspector General recommended that the VHA establish to deal with the HCV health delivery issue.

Dear Chairman Shays and members of the subcommittee, on behalf of the men and women who risked their lives for our country and who now face an even greater battle against hepatitis C and the Department of Veterans Affairs, I beg you to examine the actions that the VA has taken regarding the hepatitis C issue, and for you, the committee, to take action to ensure that the VA does what it is designed for. And I quote Joe Thompson, Under Secretary for Benefits, in the February/March issue of the VVA Veteran, "We're the ones who have been entrusted by American citizens to help veterans. That's our mission."

Mr. Chairman and members of the committee, thank you very much.

[Applause.]

[The prepared statement of Mr. Baker follows:]



**STATEMENT OF**

**Terry Baker  
Executive Director  
Veterans Aimed Towards Awareness, Inc.**

**COMMITTEE ON GOVERNMENT REFORM**

**SUBCOMMITTEE ON NATIONAL SECURITY, VETERANS AFFAIRS  
AND INTERNATIONAL RELATIONS**

**HEPATITIS C:  
ACCESS, TESTING and TREATMENT  
IN THE VA HEALTH CARE SYSTEM**

**JULY 12, 2000**

Dear Mr. Chairman and other Distinguished Guests of the Subcommittee:

On behalf of Veterans Aimed Toward Awareness (VATA), a support group for veterans with Hepatitis-C, and Vietnam Veterans of America Chapter 83, I am honored to be here a second time in regards to the VA's handling of the Hepatitis-C epidemic.

Since June 9, 1999, when we last met, I have been traveling around the country talking to veterans, offering them hepatitis C testing and counseling, visiting VA hospitals and clinics, and corresponding with Dr. Garthwaite and his counterparts. I have attended one of the VA's training on Hep-C and visited the Miami Hepatitis C Center of Excellence.

Members of the committee, other than the efforts of my organization to provide education, counseling and testing—working with some of the VA facilities, I have not seen the proactive and aggressive effort to address hepatitis C among veterans that the VA promised this Committee on June 9, 1999.

Talking with veterans, I have found that the VA's approach to treatment is only to treat those veterans who have high liver enzyme levels, those who have symptomatic liver disease, and those who are possibly beyond help, instead of treating the veterans who could benefit the most from the dual therapy. In my view the VA is treating the veterans who will benefit the least.

In fact, in a letter to this Committee dated June 28, 2000, Dr. Garthwaite seemed proud of the fact that 78% of veterans receiving treatment within the VA are designated into the "complex care" category. I believe that Dr. Garthwaite intended to impress upon you, Mr. Chairman that HCV cases are being properly reimbursed to the medical centers. Let me offer another possibility—78% of all veterans being treated fall into the complex care category because the VAMCs are treating only those veterans who are sick enough to meet the strict criteria of being a complex care patient in the VA. Furthermore, it is my humble opinion that most treatment is being reserved for complex care patients because VAMCs realize that they cannot afford to start basic care patient on the expensive therapy because they only generate \$4,000 per patient per year. They are well aware that the estimated VA HCV patient needs care with an average cost to the VA of between \$25,000 and \$40,000.



To treat HCV patients who fall into the basic care category would bankrupt the particular hospital delivering this care. The VAMCs must WAIT for their HCV patients to progress to more serious complications, like ascites, in order for the medical records of the patients to note the appropriate DRGs (diagnostic codes) to allow the VAMC to collect the complex care funding to cover HCV pharmaceutical and other costs of initiating treatment.

One of the only VISN's that treats the virus as the sole enemy is VISN 13 under the supervision of Dr. Sam Ho. If VA ever designates another Center of Excellence in Hepatitis C care, it should be Dr. Ho's. He and Dr. Petzel treat veterans with real respect and see HCV as a disease that can and should be eradicated from every veteran, no questions asked.

Following last year's hearing, we approached Dr. Garthwaite about assisting the individual VISN's with their HCV programs and helping them improve particular HCV-related shortcomings witnessed in various VISN's. He told us to direct our concerns to the individual VISN's – which we did by letters to each VISN this past March. To our surprise, instead of working with the particular VISN's on HCV as originally instructed by Dr. Garthwaite, we received one letter from VA Central Office on behalf of all twenty-two VISN's. So much for a decentralized system.

Concerning all the correspondence that we have had with Central Office, it certainly seems that someone is trying to placate me! Because there are more important matters to discuss, and there is little time now, I have submitted that material for you to review at a later date.

I have been asked to follow up on the examples that I produced last year. Mr. Chairman, I am sorry to report that these veterans' lives have gotten dramatically worse. The veteran from Idaho was finally tested, but has not yet been allowed to receive treatment in VISN 19, in fact, he has been told that despite evidence of fibrosis of the liver, his enzyme levels are not elevated enough to consider him for treatment. As for the veteran from Montana, the VA has "done a fine job" – he was never treated for his Hep-C and in November of last year, he succumbed to complications from a liver transplant due to Hep-C. I attended his funeral.

In the case of my personal friend from New Jersey that served with the 173<sup>rd</sup> Airborne, he is now number 7 on the liver transplant waiting list. Even though we personally hand-delivered his case to Dr. Garthwaite, NO, I repeat NO action has been taken! The VA continues to maintain that this recipient of the Bronze Star for

Valor can not show a nexus between his service and his hepatitis C infection because his duty assignment was not “medic.”

So much for serving one’s country and believing that one’s country will “bind up the wounds” of battle. Committee Members, I must stress that while the VA tells us that they are doing the right things and all that they can, the veterans caught in the middle of this war do not have the time for the VA to continually drag their feet. I have personally, along with some fine people, brought forth more awareness from my little office than all of the VA.

I am appalled, and take great umbrage at the duplicitous nature of the VA’s Central Office. There are solutions to these problems, and I think that if a simple, longhaired country boy like me can figure them out, so can these highly educated people. Simple things like letting infectious disease physicians actively assist in providing treatment for this disease—if the VA has a shortage of gastroenterologists then let’s use the currently underutilized infrastructure that was built within the VA to provide treatment for AIDS—let’s use them to treat HCV. After all, the therapy is very similar and HCV is an infectious disease. If we still don’t have enough manpower—let’s look at flexible hiring schemes!

Another important point to consider is that the VA should really be “One VA” when it comes to this disease. For example, a Vet from Montana should not have to relocate to Phoenix to get treatment—especially when he has fibrosis. VISN 19 should respect the standard of care in the community and provide treatment to all appropriate candidates. This means that the training, like I attended in DC, for HCV must be forced onto VA personnel from all over the country. An analysis by my organization of the 367 persons who attended the first two HCV training programs found that 43% of attendee were from the Eastern Seaboard, 28% from the central United States and only 19% from the Western states. It’s no surprise that Mr. Bryant, whose testimony you will hear today, has experienced such problems in his struggle for care in VISN 20.

For more suggestions, I’d be glad to meet with the committee and the VA to develop a more productive program for our Hep-C patients. In fact I would like to serve on the Advisory Committee that the VA Office of the Inspector General recommended that the VHA establish to deal with the HCV health delivery issues.

Dear Chairman Shays and the Subcommittee, on behalf of the men and women who risked their lives for our country and who now face an even greater battle against Hep-C and the Department of Veterans Affairs, I beg you to examine the

actions that the VA has taken regarding the Hep-C issue, and for you, the committee, to TAKE ACTION to ensure that the VA does what it is designed for – and I quote Joe Thompson, Undersecretary for Benefits, in the February/March issue of the *VVA Veteran*, “We’re the ones who’ve been entrusted by American citizens to **HELP** veterans. That’s our mission.”

Thank you.

Terry Baker, Director  
VATA  
111 West Main Street  
Middletown, DE

Mr. SHAYS. Thank you, Mr. Baker.

We are going to suspend due to the applause from the audience. I am sorry, I should have stated that before Miss French spoke.

Mr. Baker, I apologize for not properly introducing you. You are the executive director of the Veterans Aimed Toward Awareness, Inc., and also a Vietnam veteran. Correct?

Mr. BAKER. Yes, sir.

Mr. SHAYS. Also, we have Mr. James A. Bryant, a Vietnam veteran, who will speak next, and then Mr. Martin Lesinski, also a Vietnam veteran.

It is the practice of this committee to have our veterans speak before the Department speaks. We appreciate the Department waiving their protocol, in a sense, to address first. It is appreciated that they come to listen to what you have to say.

Mr. Bryant.

#### **STATEMENT OF JAMES A. BRYANT, VIETNAM VETERAN**

Mr. BRYANT. Good morning, Mr. Chairman and members of the subcommittee. I am beyond honored to be here this morning. My name is James Bryant. I am a military veteran, a 100 percent service-connected veteran for issues other than hepatitis C. I currently reside in Stevens County in Washington State. I am honored to tell you about my experiences as a veteran with hepatitis C seeking treatment through the VA health care system.

During my service in the Navy I made two 9-month cruises to the Gulf of Tonkin as an aviation fire control technician. After being medically discharged in 1973 for ulcerative colitis, which is an inflammation of the small bowel or colon, I underwent colon surgery at a VA hospital in 1978.

Mr. SHAYS. Mr. Bryant, I am going to have you start your testimony when we get back from voting. My concern is that Miss French is going to be unable to be here when we get back. There are just one or two questions that I think we would just like to quickly ask here, and then we will treat all three of you as a separate panel.

Mr. BRYANT. Absolutely. That is fine, sir.

Mr. SHAYS. Miss French, I would just start by saying that in your travels, which are extensive, you focus on entirely on veterans' issues, is that correct?

Miss FRENCH. Yes. Approximately 99.9 percent of my time is veterans' issues-related.

Mr. SHAYS. So almost every day you are in contact with veterans.

Miss FRENCH. Yes, that is true.

Mr. SHAYS. In your role, how would you evaluate the veterans' knowledge of the services that are available, and particularly as it relates to hepatitis C?

Miss FRENCH. It has been brought up to me more than a handful of times the fact that veterans do not know what they are entitled to. I just spoke with a panel of veterans 2 days ago in Allentown, PA, and they expressed their displeasure in not being able to find out about the services that could help them. When I told them about hepatitis C, they did not know about the increase in the veteran population, about the epidemic. So I do think it is something that needs to be addressed on getting information to the veterans.

We talked about several ways to do that—perhaps a data base. I understand that the VA cannot advertise their services because they are a Federal agency, however, it is a large issue.

Mr. SHAYS. I was at an event in the Fairfield/Bridgeport area of Connecticut and I was pretty amazed with how open the veterans were to you in discussing their challenges. Have you had occasion to sit down with the people from the VA and talk about what you are learning?

Miss FRENCH. Actually, I was Miss Kentucky before I was Miss America, and I was brought up to Washington and met with several of the dignitaries from the VA system nationally. What we have discussed throughout the year is my experience with the veterans, what I have seen, and we have constant correspondence. However, the meeting yesterday with the veterans produced some new questions for me to ask. One of them is, if Medicare and Social Security can advertise for increased enrollment, then why can't the VA system with their veterans? It is a concern of mine, something that I do intend to address.

They want to get hepatitis C information, they want to increase the enrollment, they want veterans to come in and get tested and treated, however there has been no action taken to increase the staffing. If we see 2,000 new veterans come into a hospital in a year or two, it has been said that they intend on keeping the same number of staff members to treat those veterans as well. I do not see that as a possibility.

Mr. SHAYS. We have limited time before we have to go vote, so I would welcome questions from Mr. Tierney and any of the other Members.

Mr. TIERNEY. Thank you, Mr. Chairman.

I do not have a question, I just want to thank you very much. I thought your testimony was well done, and you are doing a great service for everyone by using your position, I might say, to full advantage.

Miss FRENCH. Thank you.

Mr. TIERNEY. The chairman was with me on a hearing we had about community-based outreach clinics within the veterans service. I think there is more that we can do with those entities in terms of outreach on that. I suspect that there is nothing to stop any of the Members of Congress from tying it to their Web sites some information about that as a matter of outreach on that. I would think that might be one avenue for us all to pursue. And last, many of us send out newsletters periodically under our franking privilege. We sent out one that just mentioned veterans benefits for prescription drugs and got 500 phone calls the very next day. So that if we use those resources, and with your assistance, also the VA and tying those things together, we might have some success on that. So again, I want to thank you for what you have been doing, and I would defer to my colleagues if they have any questions.

Mr. ALLEN. Thank you very much. An excellent job. Just a quick question. In talking to veterans, do you find any pattern emerging, either specifically with respect to hepatitis C or any others, just in terms of the administration, how difficult it is for them to get care?

You are talking to lots of veterans and a quick question is what are you picking up?

Miss FRENCH. Right. Every other day I am in a different city across this country, and every other day I hear the same stories about the difficulties with getting treatment, difficulties in getting screened, especially filling out the paperwork. Probably my greatest displeasure is in seeing the hope being lost in veterans who for 4 and 6 weeks have to keep coming back in to the VA to stand in another line to be told that they need to wait another 4 or 6 weeks to even see a physician. That is something that is reoccurring too often. And when you think that I travel 20,000 miles a month, I think it is hitting the majority of our veterans.

Mr. ALLEN. Thank you very much.

Mr. SHAYS. Mr. Snyder.

Mr. SNYDER. Thank you, Mr. Chairman, and thank you for allowing me to participate in the hearing today.

Heather, the number that you have in here, the 365,000 blood transfusions, I assume the majority of those were probably in 1968 which was a very bloody year there. I think one of our VA witnesses later on has an anecdote there of a patient he talks about that may or may not have received a blood transfusion but when some ordinance went off, a piece of bone from the man next to him was imbedded in his leg. It seems like the tougher issues are not the transfusion issues, they are the exposure to blood issues. But I think that figure really brings home the number, that for every 365,000 that had transfusion there were a whole lot of others that were exposed to blood. The issue is how likely is it in a combat situation to acquire the virus through splattered blood if you did not get the transfusion itself.

I want to make the point too, and I know you agree with this, I think this focus on veterans and this issue is very important. As a Vietnam veteran, I feel very strongly about it. But I do not want our non-veteran population out there to somehow think they are immune from this. This was brought home to me 2 years ago when one of my employees received a call from her husband 1 day that he was not feeling well, had been in good health at age 43, and 2 weeks later passed away from undiagnosed hepatitis C. This is a very real issue out there, and not just for veterans but for our entire population, and I appreciate your work on these issues.

Miss FRENCH. Thank you. Something I would like to share with you, too. Representative Allen, you had asked what was occurring in our system. A woman wrote me a letter about her husband who in 1978 was diagnosed with non-A/non-B, which now we attribute to hepatitis C. He went back into the service, then went into the hospital again, and this is 1978 we are talking about, was discharged medically, came home and became very ill in 1997. Of course, hepatitis C can take 28 to 30 years to show any symptoms at all. He was sent away from the VA with flu.

Well, as many know, hepatitis C has flu-like symptoms. The VA failed to check his medical records to see that he was diagnosed with non-A/non-B back in 1978. So the very next day he came back into the emergency room with liver failure, had to get a liver transplant, and as this woman said, and I quote from her letter, "Again I am sorry for taking up your time and I hope that you understand

my point, because you see, Miss French, on April 23, 1999, a big part of my life died that day when my husband died." I believe that these things could be prevented with more consistent health care.

Mr. SHAYS. We have about 5 minutes to vote. You have many duties to attend to as well.

Gentlemen, we will be back to continue this panel after the vote. We stand in recess.

[Recess.]

Mr. SHAYS. Mr. Baker, we thank you for your testimony you have completed, but, Mr. Bryant, we are going to start you over again, OK?

Mr. BRYANT. Yes, sir.

Mr. SHAYS. We will go from the beginning. We have no rush, so you take your time.

#### **STATEMENT OF JAMES A. BRYANT, VIETNAM VETERAN**

Mr. BRYANT. Before I start, I want to say that I am overwhelmed with the honor and the responsibility that has been given me that I have just begun to realize in listening to stories of three people, including yourself, Mr. Shays, that I have never met before and they are all the same but were all different.

Mr. Chairman and members of the subcommittee, good morning.

My name is James Bryant. I am 100 percent service-connected military veteran and I was 100 percent service-connected for other issues before my HCV. I currently reside in Stevens County, WA. I am honored to be here to tell you about my experience as a veteran with hepatitis C seeking care and treatment through the VA health care system.

During my service in the Navy, I made two 9-month cruises to the Gulf of Tonkin as an aviation fire control technician. After being medically discharged in 1973 for ulcerative colitis, which is an inflammation of the small bowel or colon, I underwent colon surgery at a VA hospital in 1978. During this surgery to remove my colon I was given several units of blood. This blood, I am told, is my most likely point of infection with hepatitis C.

I was diagnosed with hepatitis C in 1994 when the doctors at the Spokane VA hospital told me about my hepatitis C infection. I had many questions but I received very little information and even less support. Instead, all the VA doctors said was, "Don't worry, your liver function tests are only slightly elevated so there is no reason to believe there is any on-going liver damage." In essence, don't sweat it, just don't drink alcohol. The VA doctors at the Seattle VA hospital also told me that since my LFTs were less than twice normal, I was not a good candidate for interferon treatment and they would let me know if they saw any problems developing or if there were any advances or improvements in treatment.

That was mid-1994. From then until early 1999, the VA never contacted me for any consults or check-ups regarding my hepatitis C. During that time though, I began to see an escalating theme in my life of fatigue and what I now call brain fog. Any physical exertion wore me out. I decided to do my own research on the internet. I became concerned that I really had absolutely no information about the health of my liver.

In early 1999 I went to an appointment at the Spokane VA hospital and I shared my concerns about my hepatitis C and the health of my liver with a VA doctor. I asked for a liver biopsy and a viral load test, as those were the VA's own procedures for treatment of hepatitis C. I was shocked and surprised by his answers, that: (1) This hospital has a policy of not doing liver biopsies; (2) In looking at your past LFT tests, you do not meet the protocols for interferon treatment as they are below twice normal; and (3) I will order you a viral load test and we will discuss it at your next appointment in 3 months.

On my next appointment, my viral load tests revealed high hepatitis C activity. I asked for a genotype test because some hepatitis C genotypes are much more resistant to treatment than others. This test was also refused. I did, however, get an appointment for a consultation at the GI clinic at the Spokane VA hospital. I was told that it would be a lengthy wait as there was now no full-time GI doctor at the hospital, only a part-time retired doctor handling the GI clinic.

At my first GI clinic visit, I again asked for a liver biopsy, a viral load test, and a genotyping test. Dr. Roberts apologized and said that the hospital had a policy against liver biopsies and does not, as a matter of course, do genotyping. He said he had tried with previous patients and had been refused by the hospital administration. Dr. Roberts then put me through the required hoops to rule out other possible causes for my high liver function numbers.

At my next visit to the Spokane VA hospital in early January 2000, I again asked for a liver biopsy, a viral load test, and a genotype test. The then VA physician, Dr. Pavey told me that all of these tests were a waste of time and VA money, that biopsies were risky and that I should be glad for Rebetrone treatment as it is very expensive. Finally, I started Rebetrone combination therapy January 18th of this year.

The last part of my hepatitis C story is bittersweet. The good news is that just last month viral load tests came back "undetectable," meaning a count below 8,000. The bad news is that there was not enough virus in my system for a genotype test when the VA finally did decide to run the test. Now there is no way for the doctors to determine whether I should continue with hepatitis C treatment or not. You see, different hepatitis C genotypes respond differently to treatment and dictate how long a person should remain on treatment. But in my case, they do not know because they do not have the information they need.

So they have left the decision up to me—do I continue with an extremely exhausting treatment for another 6 months, even though it may be completely unnecessary, just in case? Saving money by not testing in my case may well have cost the VA another \$7,500.

To summarize, I have found the following things to be true during the past 6 years of dealing with my hepatitis C and the VA health care system: I truly believe that had I not been the proverbial squeaky wheel, the VA would still have done nothing to follow-up my hepatitis C condition.

The VA diagnosed me with hepatitis C in 1994. To this day, however, I have no concrete evidence as to how much hepatitis C has



destroyed my liver. I really want to know what shape my liver is in.

My local VA hospital and the Seattle VA hospital lulled me into a false sense of security about hepatitis C for almost 5 years.

I am deeply concerned about access to hepatitis C care, or the lack thereof, at my local VA hospital. According to Spokane VA hospital staff who do not wish to be named, more than 60 hepatitis C-positive veterans are waiting for their first appointment with a GI doctor, but only 3 veterans, including myself, are currently being treated at that hospital for hepatitis C. There are currently about 250 people waiting for appointments in the GI clinic. From January to the end of May 2000, only one doctor worked 2 days a week seeing all of the hepatitis C and GI patients, and then only in the afternoon. For the entire month of June no hepatitis C doctor was on staff. Now there is another temporary replacement doctor but only for the next 2 months. I cannot be certain, but I have spoken to other veterans who say this is the typical situation at their VA hospitals too.

The VA may be moving in the right direction but things could be much better. How many veterans have lost their lives because the VA told them not to worry, hepatitis C is not a big thing. How many of my brothers and sisters are in end-stage liver disease because the Veterans Administration has dropped the ball, never followed up on their hepatitis C conditions, or tested them in the first place, or counselled them on how important it is to refrain from alcohol and drug use because of their hepatitis C.

I read somewhere that complacency is hepatitis C's best friend. That is precisely what the VA cannot be—complacent. Veterans need full-time doctors focused on just hepatitis C in every VA hospital in the country. Veterans need a consistent plan of treatment for hepatitis C so that no matter where a veteran goes for treatment they will get the same high quality care for hepatitis C.

I wish to thank the members of this committee for inviting me to speak about my personal experiences regarding hepatitis C and the VA. I also want to thank Congressman Nethercutt and Senator Murray for answering my letters regarding this matter, especially Congressman Nethercutt for contacting the Spokane VA to find out for himself what was going on.

[The prepared statement of Mr. Bryant follows:]

**STATEMENT OF**

**James A. Bryant**

**COMMITTEE ON GOVERNMENT REFORM**

**SUBCOMMITTEE ON NATIONAL SECURITY, VETERANS AFFAIRS  
AND INTERNATIONAL RELATIONS**

**HEPATITIS C:  
ACCESS, TESTING and TREATMENT  
IN THE VA HEALTH CARE SYSTEM**

**JULY 12, 2000**

Mr. Chairman and Members of the Subcommittee:

Good Morning. My name is James Bryant. I am a military veteran and currently reside in Stevens County in Washington State. I am honored to be here to tell you about my experiences as a veteran with hepatitis C seeking care and treatment through the VA health care system.

I entered the US Navy in January 1965 and went to boot camp in San Diego, California. I believe the air gun shots given to all recruits to be the first of several possible ways I contracted hepatitis C. I remember lining up for those shots and seeing many recruits, including me, bleeding from the shoulder after the air gun shot. After boot camp, I went to aviation electronic schools near Memphis. While stationed in Virginia Beach in late 1966, I spent time in Portsmouth Naval Hospital for mononucleosis, also involving the liver. I think it was here that I was informed that I had "non-a, non-b hepatitis" -- the old name for hepatitis C.

During my service in the Navy, I made two nine-month cruises to the Gulf of Tonkin as an Aviation Fire Control Technician. Before leaving for Viet Nam, we received our overseas inoculations. One was for yellow fever, which I believe is being looked at in connection with hepatitis C.

I returned to civilian life in January 1969 and worked in the electronics industry in Southern California. I returned to the Navy in early 1971 and was again stationed in Virginia Beach. While stationed there, I was hospitalized for ulcerative colitis, an inflammation of the small bowel or colon. After my course of treatment I was declared unfit for sea duty and told it would be best for me and the Navy if I got out on a temporary disability retirement list. After about 18 months of relatively few problems I was given a medical discharge. I was rated at 0% by the

Navy but 10% by the VA for ulcerative colitis.

My experience with the VA medical system began in mid-1974. Several times between 1974 and 1978, I was hospitalized for flare ups of my colitis which eventually led to my colon being removed in 1978. During the colon surgery I was given several units of blood. This blood, I am told, is my most likely point of infection with Hepatitis C. However, it is medically impossible to pinpoint exactly where, when or how I got infected with HCV. I believe I contracted it during my first enlistment in the Navy. I base this opinion on the progression of symptoms of fatigue and mental confusion I can remember since early in my first enlistment. Sadly, until I was diagnosed with HCV in 1994, I was told and I believed that it was all in my head.

When the docs at the Spokane VAMC told me about my hepatitis C infection, I had many questions but I received very little information and even less support. Instead, all the VA doc said was: "Don't worry, your liver function tests (LFT's) are only slightly elevated so there is no reason to believe there is any on-going liver damage. Don't sweat it. Don't drink alcohol." By the way, I had stopped drinking any alcohol in 1992. The VA docs at the Seattle VAMC also told me that since my LFT's were less than twice normal, I was not a good candidate for interferon treatment. They said they'd let me know if they saw any problems developing or if there were any advances or improvements in treatment.

That was mid-1994. From then until early 1999, the VA never contacted me for any kind of consults or check-ups regarding my HCV. During that time though, I began to see an escalating theme in my life of fatigue and what I now call brain fog. Any physical exertion wore me out.

At the same time, I started hearing things about hepatitis C from other sources. I decided to try to find out what I could on my own on the Internet. I became concerned that I really had absolutely no information about the condition of my liver.

In early 1999 I went to an appointment at the Spokane VAMC. I told the VA doc of my concerns about my Hep C and the health of my liver. I asked for a liver biopsy and viral load test, as those were the VA's own procedures for treatment of HCV. I was shocked and surprised by his answers:

1. This hospital has a policy of not doing liver biopsies.
2. In looking at your past LFT tests, you do not meet the protocols for interferon treatment as they are below twice normal.
3. I will order a viral load test and we will discuss it at your next appointment in three months.

On my next appointment, my viral load tests revealed high HCV activity. I asked for a genotype test because I had learned through my own research that some HCV genotypes are much more resistant to treatment than others. This test was also refused. I did, however, get an appointment for a consult at the GI clinic at the Spokane VAMC. I was told that it would be a lengthy wait as there was now no full-time GI doctor at the hospital since Dr. Pavey had retired -- only a part-time retired doctor handling the GI clinic.

At my first GI clinic visit, I found Dr. Roberts to be very knowledgeable about Hep C. He confirmed that my LFT's were now twice the normal count. I asked again for a liver biopsy, a viral load test and a genotyping test. He said he was sorry but that the hospital has a policy

against liver biopsies and does not, as a matter of course, do genotyping. He said he had tried with previous patients and had been refused by the hospital administration. Dr. Roberts then put me through the required tests to rule out other possible causes of my high LFT's. The next time I saw him, he recommenced Rebetron combination therapy. He also told me that his last day at the hospital would be Nov. 15<sup>th</sup>, 1999. I saw him for the last time the day before he left.

Dr. Pavey returned to the Spokane VAMC in early January 2000. Again I asked for a liver biopsy, viral load tests and a genotype test. Dr. Pavey told me that all of these tests were a waste of time and VA money, that biopsies were not without risk and that I should be glad for the Rebetron treatment, as it is very expensive. Finally, I started Rebetron combination therapy January 18, 2000.

The last part of my HCV story is bittersweet. The good news is that just last month, viral load tests came back "undetectable," meaning a count below 8000. The bad news is that since the VA never performed a genotype test, there is no way for the docs to now determine whether I should continue with HCV treatment or not. You see, different HCV genotypes respond differently to treatment and dictate how long a person should remain on treatment. But in my case, they don't know because they don't have the information they need. They have left the decision up to me. Do I continue with an extremely exhausting treatment for another six months even though it may be completely unnecessary just in case? Saving money by not testing, in my case, may well have cost the VA another \$7500.

To summarize, I have found the following things to be true during the past six years of dealing with my hepatitis C:

1. I truly believe that had I not been the proverbial "Squeaky Wheel," the VA would still have done nothing to follow-up on my HCV condition.
2. The VA diagnosed me with HCV in 1994. To this day, however, I have no concrete evidence as to how much HCV has destroyed my liver. I would really like to know the condition and health of my liver.
3. My local VA hospital and the Seattle VA hospital lulled me into a false sense of security about HCV for almost five years.

I am deeply concerned not only for myself but for other vets who may still be awaiting their first appointment in Spokane to see a HCV doctor. According to staff at the Spokane VAMC who do not wish to be named, more than 60 veterans are waiting for their first appointments with a GI doctor but only three vets, including myself, are currently being treated for HCV. There are currently about 250 vets waiting for appointments in the GI clinic. Dr. Pavey stayed on as the only GI doctor on staff at the Spokane VAMC from January to the end of May. He worked two days a week seeing patients only in the afternoon. Until the end of June, there was no HCV doc on staff. Now there is another temporary replacement doctor for only the next two months. I can't be certain but I have spoken to other veterans who say this is the typical situation at their VAMC's too.

I think things could be much improved in how the VA is handling HCV. They may be moving in the right direction but how many vets have lost their lives because the VA told them not to worry, its not a big thing. How many of my brother and sisters are in end-stage liver disease because the VA dropped the ball and never followed up on their HCV condition? Or tested them in the first place? Or counseled them on how important it is to refrain from alcohol or drugs

because of the HCV?

I read somewhere that complacency is hepatitis C's best friend and helper. That is precisely what the VA cannot be -- complacent. Veterans need full-time doctors focused just on hepatitis C in every VAMC in this country. Veterans need a consistent plan of treatment for HCV so that no matter where a veteran goes for treatment, they will get the same high-quality care for hepatitis C.

I wish to thank this committee and its members for inviting me to speak to you about my personal experience and concerns HCV and the VA. I also want to thank Congressman Nethercutt and the Senator Murry for answering my letters. Especially the Congressman Nethercutt for looking into the Spokane VAMC's lack of a full-time GI doctor or hepatologist.

Thank you.

James A. Bryant  
3622 Lane Mountain Way  
P.O. Box 160  
Valley, WA 99181-0160



Mr. SHAYS. Thank you, Mr. Bryant.  
Mr. Lesinski.

**STATEMENT OF MARTIN P. LESINSKI, VIETNAM VETERAN**

Mr. LESINSKI. Thank you, Chairman Shays and members of the subcommittee. My name is Martin Lesinski. Thank you for this opportunity to speak of my personal experiences with hepatitis C. I hope my testimony will be of benefit not only to fellow disabled veterans, but also to the honorable Congressmen who play so principal a role in determining the quality of their lives. Following my testimony, I welcome your questions and concerns.

I am a disabled veteran of the Vietnam war. My service-connected disabilities include hepatitis C. I served as an Army infantry sergeant in Vietnam from the fall of 1970 until being wounded near the end of February 1971. I stepped on a booby trap, received multiple fragment wounds which required several blood transfusions, both in-country in Vietnam and also later in the Philippines. At my annual VA blood draw in March 1998, my liver function tested abnormal. A followup test for hepatitis C revealed I was positive. Until hearing this diagnosis, I was essentially unaware of hepatitis C, its causes, and its potentially fatal consequences.

As a veteran, one returns from war either dead or alive; and if fortunate to be alive, either wounded or not. Here's the thing, if you are wounded, you made it home alive, you know the extent of your injuries, your disabilities, and there is no further risk of death. Well, that is what I thought before this diagnosis. It was a shock. After nearly 30 years of living with my service-connected disabilities, suddenly there is a new consequence of my service— hepatitis C, and this one can kill me. It really took some adjusting.

In June 1998, I was referred to the Liver Clinic at the San Francisco VA Medical Center and came under the care of Dr. Teresa Wright. A liver biopsy was performed. My liver was enlarged and early stage scarring had occurred and was continuing. I was experiencing increasing fatigue and weakness.

At this point my situation got complicated and challenging. My hepatitis C was severe enough that I required treatment. I was screened for admission into a research study program being conducted by Dr. Wright through the VA. Unfortunately, given the extent of my PTSD, for which I am 70 percent service-connected, I was rejected. Great disappointment. What to do and how to obtain treatment?

Fortunately, during this process the FDA approved combination therapy for naive patients. But even more fortunately for myself, I reside in San Francisco, one of the two Hepatitis C Centers of Excellence, and where Dr. Wright was able to make treatment available to me.

In February 1999, I began combination therapy, continuing through August. The treatment was extremely debilitating. It is disheartening to be 6'4", 200 plus pounds and unable to climb a single set of stairs without resting mid-flight. There were weeks when I just could not get out of bed except to go to the bathroom. It was November 1999 before my blood counts returned to normal. Six months after the completion of treatment I was virus free and

my liver functions normal. Quite simply, I have gotten my life back. I am the fortunate one. I have returned to my base line disabilities, the non-fatal ones.

Mine is a success case in the treatment of hepatitis C. Unfortunately, I have also learned that simply obtaining hepatitis C treatment from the VA can in itself be considered a success. It should not be. Think about it—2 years after being diagnosed with a debilitating disease, I am testing virus free. I know that had it not been for several key factors falling into place at the right time, I would not be here before you with my hepatitis C currently in remission. A number of factors converged—annual blood testing necessitated by my other combat injuries which detected my liver problems, living in San Francisco VA region where hepatitis C treatment is available, coming under the excellent care of Dr. Teresa Wright, a broad support team during my treatment, and believe me, the prayers of many.

However, I should not be the only fortunate one. I believe screening and treatment for hepatitis C should be uniformly available throughout all VA medical centers, and readily available to all veterans exposed to any risk factors associated with their military service. Until hepatitis C is viewed as a disease that affects all veterans, Congress will continue to witness and veterans will continue to experience this disparate level of care for hepatitis C within the VA's regions.

This disease is not only destructive, but asymptomatic, often stealth-like until far advanced. Such a disease requires a broad and uniform access to screening for the entire veteran community. Hepatitis C is a silent killer. Only in looking back after my hepatitis C diagnosis did it become apparent to me that the fatigue and abdominal discomfort I was experiencing was the result of a fatal virus, and not simply the demands and stress of my daily job. How many other veterans are unknowingly enduring these symptoms, carrying this additional burden daily for having answered their country's call?

Veterans are not just fellow Americans. We are the sons and brothers, the daughters and sisters in families across America. No matter the individual circumstances, we answered our country's call at a time when the options not to step forward were more numerous, more available, and more broadly supported than ever before. As young men and women, we put on the uniforms and shouldered the responsibilities of soldiers, sailors, airmen, and marines. Twenty-five years after the end of the Vietnam war America's veterans, America's sons and daughters continue to pay the physical and psychological costs of their service.

I ask you honorable Congressmen and your colleagues to provide the necessary oversight and resources for a consistent and comprehensive hepatitis C treatment program for all of America's veterans, not just those veterans lucky enough to be living in select VA regions, but for all veterans across America. It is particularly painful for us to be denied medical treatment in this time of surplus.

I want to thank this committee and you, Chairman Shays, for your attention to this critical issue. I applaud this committee's oversight to ensure that veterans receive quality access, testing,

and treatment for hepatitis C. This I ask of you: May not just the fortunate ones, but all veterans be provided unwavering screening and treatment for hepatitis C throughout the VA health care system. Please grant all veterans the opportunity to live their lives to their full potential. Thank you.

[The prepared statement of Mr. Lesinski follows:]

**STATEMENT OF**  
**Martin P. Lesinski**  
**COMMITTEE ON GOVERNMENT REFORM**  
**SUBCOMMITTEE ON NATIONAL SECURITY, VETERANS AFFAIRS**  
**AND INTERNATIONAL RELATIONS**

**HEPATITIS C:**  
**ACCESS, TESTING and TREATMENT**  
**IN THE VA HEALTH CARE SYSTEM**

**JULY 12, 2000**

Dear Chairman Shays and Members of the Subcommittee:

Thank you for this opportunity to speak of my personal experiences with Hepatitis C. I hope my testimony will be of benefit not only to fellow disabled veterans, but also to the honorable congressmen who play so principle a role in determining the quality of life for America's veterans. I am grateful that the honorable congressmen are taking the time to fully understand the complex issue of managing hepatitis C within the VA health care system. Following my testimony, I welcome your questions and concerns.

I am a disabled veteran of the Vietnam War. My disability includes service connection for Hepatitis C. I served as an Army infantry sergeant in Vietnam from the Fall of 1970 until being wounded near the end of February, 1971. I stepped on a booby trap receiving multiple fragment wounds and requiring several blood transfusions. As a result of my injuries, I have been on anti-inflammatory drugs the past 20 years. Consequently, my liver and kidney functions have been monitored periodically. At my annual VA blood draw in March of 1998, my liver functions tested abnormal. I was retested several weeks later. Among the tests run at that time was one for hepatitis C. The results were positive. Until hearing this diagnosis, I was essentially unaware of Hepatitis C, its causes and its potentially fatal consequences.

As a veteran, one returns from war either dead or alive; and if fortunate to be alive, either wounded or not. The thing is this. If wounded, you've made it home alive, you know the extent of your injuries, your disabilities, and there is no further risk of death. Or so I thought before this diagnosis. It was a shock that after living nearly 30 years with my service connected disabilities, there was suddenly a new consequence of my service – hepatitis C; and this new one could kill me. It took some adjusting.

In June of 1998, I was referred to the Liver Clinic of the San Francisco VA Medical Center and came under the care of Dr. Teresa Wright, Associate Professor of Medicine

and Chief of Gastroenterology. A liver biopsy was performed by Dr. Wright in May 1998, and the extent of my liver damage was recognized. My liver was enlarged and early stage scarring had occurred. I was experiencing increasing fatigue and weakness.

At this point, my situation got complicated and challenging. I became proactive in educating myself about the hepatitis C virus. There were two courses of treatment at that time. One was solely Interferon therapy, the low success and high relapse rates of which didn't make the side effects worth it. The other was combination therapy, using Interferon simultaneously with Ribavirin. However, I was a "naive" patient; i.e., I had not received any previous treatment for Hepatitis C. The FDA had not approved combination therapy for naive patients. What to do? Dr. Wright offered the chance to enter a research study being conducted through the VA. I was screened for admission. Unfortunately, given the extent of my PTSD (Post Traumatic Stress Disorder) for which I am currently 70 percent service-connected, I was rejected. Great disappointment! Again, what to do? How to obtain treatment? Fortunately, during this process, the FDA approved combination therapy for naive patients. Even more fortunately, I reside in San Francisco, one of the two VA Hepatitis C Centers of Excellence; and where Dr. Wright was able to make treatment available to me. Having genotype 2b of the HCV virus, only six months treatment was required and my chances of success were higher than with the other genotypes.

In February of 1999, I began combination therapy, continuing through August. The treatment was extremely debilitating. It's disheartening to be 6'4", 200 plus pounds and unable to climb a single set of stairs without resting mid-flight. There were weeks when I didn't get out of bed except to go to the bathroom. It was November, 1999 before my blood counts returned to normal. Six months after the completion of treatment I was virus free and my liver functions normal. Quite simply, I've gotten my life back. The weakness, abdominal pain and increasing fatigue I experienced before treatment are

absent. My energy has returned. I have the best possible prognosis at this point in time. I've returned to my base line disabilities, the non-fatal ones.

Mine is a success case in the treatment of hepatitis C. Unfortunately, I've also learned that simply obtaining HCV treatment from the VA can in itself be considered a success. It should not be. Think about it: within two years after being diagnosed with a debilitating disease, I am testing virus free. I know that had it not been for several key factors falling into place at the right time, I would not be here before you with my hepatitis C currently resolved. A number of factors converged for me: annual blood testing necessitated by my other combat injuries which detected my liver problems, living in the San Francisco VA region where hepatitis C treatment is available, coming under Dr. Teresa Wright's care, a broad and deep support team during my treatment, and the prayers of many.

However, I should not be the only fortunate one. I believe screening and treatment for hepatitis C should be uniformly available throughout all VA medical centers; and readily available to all veterans exposed to any risk factors associated with their military service. Until hepatitis C is viewed as a disease that affects all veterans, Congress will continue to witness and veterans will continue to experience the disparate levels of care that HCV is currently given among the VA's regions. This disease is not only destructive, but also asymptomatic, often stealth-like until far advanced. Such a disease requires a broad and uniform access to screening for the entire veteran community. Hepatitis C is a silent killer. Only in looking back after my Hepatitis C diagnosis did it become apparent the fatigue and abdominal discomfort I was experiencing was the result of a fatal virus, and not simply the demands and stress of my daily job. How many other veterans are unknowingly enduring these symptoms, carrying this additional burden daily for having answered their country's call?

I have heard of fellow veterans being told that their VA doctors couldn't treat them because there wasn't enough funding. This lack of funding at local VA medical centers

shocks and concerns me. I know that Congress has allotted the VA up to \$350 million for HCV-related programs. Then why are America's veterans not being uniformly screened and treated for HCV? I believe all veterans should be given whatever resources are necessary to return their lives to their full potential. I applaud this committee's oversight to insure it.

After all, veterans are not just fellow Americans. We are the sons and brothers, the daughters and sisters in families across America. No matter the individual circumstances, we answered our country's call at a time when the options not to step forward were more numerous, more available and more broadly supported than ever before. As young men and women, we put on the uniforms and shouldered the responsibilities of soldiers, sailors, airmen and marines. Twenty-five years after the end of the Vietnam War America's veterans, America's sons and brothers, daughters and sisters continue to pay the physical and psychological costs of their service.

I ask you honorable congressmen and your colleagues to provide the necessary oversight and resources for a consistent and comprehensive hepatitis C treatment program for America's veterans – not just for those veterans living in select VA regions, but for all veterans across America. All of us who put on America's uniforms, who shouldered the defense of her families and prosperity continue to pay unanticipated physical and psychological costs each day. It is particularly painful to us to be denied medical support and treatment in this time of surplus. This I ask of you: May not just the fortunate ones, but all veterans be provided unwavering screening and treatment for hepatitis C throughout the entire VA medical system. Please grant all veterans the opportunity to live their lives to their full potential.

Thank you!

Martin P. Lesinski  
marski3@aol.com



Mr. SHAYS. Thank you, Mr. Lesinski.

We will begin with Mr. Tierney, Mr. Allen, and Mr. Snyder, and then I will ask some questions.

Mr. TIERNEY. Thank you, Mr. Chairman.

Gentlemen, I am very concerned about the complacency issue here, the aspect that it is your worst enemy if you have hepatitis C. I note the committee took a review of some of the veterans agents in my district and some of the clinics up there, and what we noted, from the agents at least, is they do not see much in terms of outreach, particularly from the VISNs. They might catch a letter occasionally from the Armed Services newsletters or whatever.

What would your respective recommendations be as a way to reach out to veterans and to let them know about the wisdom of having a test, the need for it, and so on down the line on that. I will start with you, Mr. Baker.

Mr. BAKER. We gave those suggestions the last time we were here, which is simple posters and brochures, which the VA told us they were going to do. To date, we still have not seen a brochure or a poster. Like I said, my mere office, I have posters and brochures here that we send out all across the country to different clinics and different VA physicians asked us for them.

Mr. TIERNEY. Mr. Bryant.

Mr. BRYANT. I do not know that I have an answer for you. In the last few months, I have seen a few pamphlets at my VA hospital. I feel like the gentleman on my left, I feel like one of the lucky ones. I just happened to be in the right place at the right time and asked the right questions. Otherwise, I think I would still be sitting there complacent if I had not, for my own reasons, gone on the Internet and found the information myself.

Mr. TIERNEY. There is nothing that the Veterans Administration had done that prompted you to do that?

Mr. BRYANT. No. I have been a service-connected disabled veteran, or at least partially so, since 1974. I have received on other matters better treatment in the VA than I think I got in civilian hospitals for various things. And up until this hepatitis C thing, I would never have been here to say anything bad about the VA because I felt almost like royalty. I was treated well for things that were not even service-connected. I ran out of money after a motorcycle accident and they took care of my leg. But I feel like there was a brick wall on this. So I am sorry, sir, I do not have an answer for you.

Mr. TIERNEY. OK. Thank you.

Mr. Lesinski.

Mr. LESINSKI. Excuse me, Mr. Tierney, I did not quite hear your question.

Mr. TIERNEY. It was for suggestions as to what could be done specifically in terms of better outreach. I take it that you did not get prompted to have your tests because you heard anything in particular from the Veterans Administration or clinics or hospitals.

Mr. LESINSKI. No, it actually came up in the course of normal annual blood work for other service-connected. I think the heart of the matter really is within the VA and the fact I realize how extremely fortunate I am in being in San Francisco, that it just fell

into place. I just feel that the VA should have this in place everywhere. We should not have to be doing additional outreach to say to veterans, hey, you might be a problem here. We should just be checking them.

Mr. TIERNEY. Thank you. I note that in my district at least they do check in all of the clinics and the hospitals. If that is not the case nationwide or whatever that they check, then we are fortunate to have Dr. Ignello down at the Bedford facility who runs the hepatitis C clinic and basically does followup on that if somebody tests positive. The one thing he does talk very carefully about is the recommendation that testing be done very early. It is asymptomatic early on and that the longer you wait the more likely you are to have serious liver damage, and also the prospect of warning them against alcohol and things of that nature if they are subject to having this situation.

So I would suspect we will probably want to have some questions for the Veterans Administration about the depth of their testing and why it is not done everywhere, and what they can do about following up on that.

Mr. Baker, you want to add something?

Mr. BAKER. That is why we suggest and we feel it should be a one VA on this issue. Like you are saying, where you are there is outreach and they are testing. There are facilities across the country that are so inconsistent with everybody else's policies, the guys just do not even know what is going on. There is not random testing in every facility. And even after the facilities do test, some of them still tell the guys to go home and they will have a notice that they will have a clinic in 6 months. Some of these veterans do not have time for 6 months. So the VA has to be consistent with their policy everywhere, and they are not.

Mr. TIERNEY. Thank you. Thank you, Mr. Chairman.

Mr. LESINSKI. If I might add something to Mr. Tierney's question. Perhaps one place for them to start in terms of concrete things to be done, since we know the blood supply was not really cleaned up until about 1990–1991, they could easily go through their records and send a letter to anyone who has received any kind of blood work or blood transfusions through their system up until that time to come in and do testing and be screened. I am sure they have that data base. I know it would incur great numbers, but that alone would identify everything.

Mr. TIERNEY. Thank you.

I yield back, Mr. Chairman.

Mr. SHAYS. Mr. Allen.

Mr. ALLEN. Thank you, Mr. Chairman.

Mr. Baker, in your testimony you say that you found the VA's approach to treatment was to treat only those veterans who had high liver enzyme levels or those who have symptomatic liver disease. I am wondering if you are suggesting that the treatment guidelines for the VA should be modified, and, if so, how they should be modified.

Mr. BAKER. They definitely should be modified. Some facilities, even the facility that I am at, if you do not have high liver enzyme levels, you are not going to go any further. The data shows, and I gave it to the committee, that in 30 percent of the cases there is

no liver enzyme elevation, so these fellows just continue to go on. I have an instance in my own facility like the one in Montana—liver damage, slighted elevated enzyme levels, they told him to go home, nothing to worry about.

They need to change their guidelines. They need to be consistent with the other leading hepatologists across the country that are not within the VA system. What it shows us is that they are only taking the sickest ones so they can get the \$40,000 that complex care patients get. The bottom line, we all know, is dollars and cents sometimes with a lot of these people. There are good people in the VA; I work with them. But something is wrong in this picture with hepatitis C. Those veterans are not out there getting treated properly.

Mr. ALLEN. How often does the issue of whether the condition is service-connected or not arise with veterans in your case?

Mr. BAKER. In my case, because I am a service officer, it arises every time I talk to a veteran with hepatitis C. I want to know what his risk factors are and if he knows what his risk factors are. There are a lot of veterans out there that cannot find a risk factor, but there are others, like we said, combat veterans with no transfusions, some were wounded, some not, but we know in a combat scene everybody has got something.

Mr. ALLEN. Mr. Snyder has some legislation that he can talk about but that would be helpful.

I yield back. Thank you, Mr. Chairman.

Mr. SHAYS. Thank you.

Mr. Snyder, you have the floor.

Mr. SNYDER. Thank you, Mr. Chairman.

Mr. Bryant, in your testimony you make mention of having had several units of blood during a surgery and that, in the opinion of some, is where they think was your most likely point of infection with hepatitis C. Of course, there are a lot of good reasons for that. But you also make the point that it is impossible for us ever to know for sure. I think that is the challenge that so many of our veterans have, is this is like the game of Clue but you never know the answer. There is a point in time at which infected veterans received that virus. We can play odds and say it must have been during that transfusion, but the reality is it is very difficult because of our state of knowledge up until 10 years ago or so to know when that point in time was. I appreciated your candor about the fact that you are not really sure when you got it either.

I want to ask a little broader question than Mr. Tierney did. For each of you, if you were the new Secretary of Veterans Affairs, or a member of this committee or the Veterans Committee, what would be your No. 1 specific priority in this whole area of hepatitis C and the VA?

Mr. BAKER. My No. 1 priority would be to just get the word out to every veteran that they need to be tested. Whether they get tested through their local insurance that they have, or come into a VA. We have an epidemic here and the first thing is to identify who has it and who does not.

From there, we straighten up our guidelines properly to coincide with what the regular population is doing, and we treat these people so that they do not become symptomatic to when they are in

the hospitals and it is costing the Department of Veterans Affairs and the taxpayers thousands and thousands of dollars to take care of these guys. Myself, I got treated in time. I am OK. The other fellows here, we have been treated in time. But we are the fortunate ones. So we need to get the word out first. And that was supposed to have been done.

Mr. SNYDER. Mr. Bryant.

Mr. BRYANT. I want to go back to something that you said about where we might have gotten it. I believe personally that I probably contracted it in boot camp with either air gun shots or a gamma globulin shot. But that does not really matter to me now. But there are people out there, and I look at the rest of my life other than my military service and the fact that I was in a VA hospital for surgery for a service-connected-related disability, and they tell me that is the most possible place, but how many people just like me went to boot camp, got a few shots. I worked in an air conditioned shop on board a carrier fixing bombing and navigation computers for the A-6. I got out and went home and was fortunate enough to have gone back in the service when I came down with ulcerative colitis. So there was no doubt that I had a direct link to it. But how many of my brothers and sisters went in, did their time, did not have any known risk factors, but they have hepatitis C. They went out and behaved themselves, they did not do drugs, they did not drink alcohol, they did not do any of the other things they said are risk factors. But they are going to die of hepatitis C all the same.

Mr. SNYDER. Thank you.

Mr. Lesinski, do you have a specific No. 1 priority?

Mr. LESINSKI. Yes, Congressman Snyder. I would make the first priority uniform screening and testing. It has just got to happen. We cannot let the unlucky ones go.

Second, I would broaden, as you spoke to earlier, and Jim Bryant just spoke to, the risk factors and exposure points. Mine was a clear-cut case where I had blood transfusions. I had been exposed to blood on the battlefield. I had no other risk factors. But it should be uniform screening and testing as the No. 1 priority, and under that, to broaden it. If someone is exposed to any of the risk factors, they should be brought in for screening.

Mr. SNYDER. Thank you. Thank you, Mr. Chairman.

Mr. SHAYS. Thank you, gentlemen.

The value of your testimony it seems to me is to now have the VA respond to it. I think your testimony and the questions that have been asked make it very clear that the protocol that we have is not really being followed. I guess I want to ask each of you why you think we need to have two hospitals that specialize in hepatitis C care when we do not have our veterans who have hepatitis C just in those areas.

I will start with you, Mr. Baker.

Mr. BAKER. First of all, I think there should be more than two Excellence Centers if they are going to lead the way in how the VA treats their veterans with hepatitis C. But again it comes down to uniformity within the VA. One facility does one thing, another one does another. It is just so scattered. If we are going to have Excellence Centers, and I visited Dr. Ho's Excellence Center as well, he

is doing an excellent job up there, but nobody even follows what he is doing. Everybody is on a different page.

The VA needs to get on the same page. I do not know what is so hard about getting on the same page and all of them following the criteria that is out there. Leading hepatologists in the world have shown the VA what criteria to follow and they choose to follow their own. Do not understand that. But I know that they need to be on the same page, all these facilities. Let's make them all Centers of Excellence, because if they are all on the same page they are all doing the right thing.

Mr. SHAYS. Mr. Bryant.

Mr. BRYANT. I think I have to echo both of these gentlemen's words. I am not nearly as eloquent. I can only reiterate that I do not think that the VA would have treated me had I not stepped up and said here I am and I need treatment. I have a son in the military now and he has yet to be tested for hepatitis C. I know people in different parts of the country, only because I talk to them on the computer, who not only had no outreach from the VA, but they cannot even get service-connected because they have to wait 2 years for an appointment to be service-connected. But they are going to die before their appointment comes up because they cannot get treatment for something that I think every one of us in this room, or at least from here forward, knows is service-connected. That may not be quite the answer to your question, but it was what was on my mind.

Mr. SHAYS. Thank you.

Mr. Lesinski.

Mr. LESINSKI. Simply make every region a Center of Excellence. That is all we need to do. It is easy.

Mr. SHAYS. Again, your testimony is very powerful. If what you have encountered is indicative of the problem other veterans encounter, it is a strong indictment that the protocol is just not being practiced.

Yes, sir?

Mr. BAKER. I would just like to add one thing, and Miss French brought this up, and that is the issue of the funds and how the VA Central Office has sent it down to their VISNs. I was at the Miami facility as well when they told us that they did not have the money. We had corresponded with VA at an earlier date about that and had been told that more money was sent. We need to make these VISN directors accountable for this money that is designated for hepatitis C. That \$350 million that was supposed to go to help toward that has gone to a lot of other places, and we know that. So we need to really make them accountable and somehow designate that this money is exactly for that purpose, not for parking lots, not for a bunch of people to go to different places in the country to supposedly take care of certain issues.

Mr. SHAYS. Any other comments any of you would like to add?

Mr. BRYANT. Yes, sir. I have not been involved in this nearly as long as any of these other people here. I have never met them before the last day or so. But everything that they said about lack of treatment, lack of outreach I have found true in my own life and with people whom I have talked to.

My VA hospital chooses not to do liver biopsies, until the last month or so they chose not to do viral load testing or genotyping. I think, pardon my French, but it is going to come back and bite them in the butt because now they are going to find out that the little things that they did not do before are going to end up costing them more money. I have got to do 6 more months of treatment that I do not want to do because they cannot tell me whether I should stop or not.

Mr. SHAYS. Mr. Lesinski, we are going to have three recorded votes, but go ahead.

Mr. LESINSKI. Chairman Shays, two things very quickly. One is, they do know how to do it right. I am sitting here because they do know how to do it right. They can do it right. They need to do it right uniformly. And second, the other thing I would like to say in closing, is once again I would like to applaud this committee for your efforts and oversight in assuring that veterans get the resources they need to live to their full potential. Thank you, gentlemen.

Mr. SHAYS. Thank you. I just would use that as an occasion to say that we first became aware of this problem when we had a hearing on the safety of the blood supply. We were looking at the HIV/AIDS virus and in there was just an off-handed comment that 300,000 people had become infected with hepatitis C and that a good chunk of them were veterans. And that is kind of how we learned of it and that is how we began to followup. It is an extraordinarily important issue, and I appreciate all three of you willing to be here and testify. Thank you very much, gentlemen.

I think we will try to get in at least the first testimony of the next panel. So if we could call our next panel, which will be Dr. Thomas V. Holohan, Chief of Patient Care Services Officer, Veterans Health Administration; Dr. Samuel B. Ho, staff physician, Minneapolis VA Medical Center; Dr. Norbert Brau, staff physician, Bronx VA Medical Center; and Dr. Frank Iber, Hepatologist, a volunteer at Hines VA Medical Center, Hines, IL.

Thank you, gentlemen. We will swear you in. If you would raise your right hands, please.

[Witnesses sworn.]

Mr. SHAYS. Thank you. Note for the record that all witnesses responded in the affirmative.

We will start with you, Dr. Holohan. I think we will hear your testimony and then we will break for the vote and come back.

Let me state again for the record there is a protocol that usually has the executive branch go first. We appreciate your willingness to listen to the witnesses. That way we will not have to ask some of the questions and then have to bring you back up afterwards. So it serves our purpose well and I hope yours, too. So thank you very much for your cooperation.

Dr. Holohan, you have the floor.

**STATEMENT OF DR. THOMAS V. HOLOHAN, M.D., CHIEF, PATIENT CARE SERVICES OFFICER, VETERANS HEALTH ADMINISTRATION, ACCOMPANIED BY JIMMY NORRIS, CHIEF FINANCIAL OFFICER, VETERANS HEALTH ADMINISTRATION**

Dr. HOLOHAN. Thank you, sir. Let me begin by making a personal comment. I am a Vietnam-era veteran, 70 percent service-connected. I thought that was an important statement to make given the tenor of the testimony we are hearing.

VA has already submitted written testimony for the record. What I would like to do at this time, Mr. Chairman, is to briefly summarize some of that information and then address the additional questions that were submitted by your staff on July 7th.

Since our last testimony to this subcommittee in June 1999, we have achieved a number of goals in our attempts to establish a national system-wide and an evidence-based approach to this disease.

We have established the Emerging Pathogens Registry as our primary mechanism for tracking both hepatitis C testing and those individual patients who have been shown to have the disease. This Registry uses an automated computer program that forwards the information to a central data base. We have reviewed and updated our treatment guidelines, and have put in place a risk assessment reminder system to improve our diagnostic capabilities.

Our Centers of Excellence in Miami and San Francisco have developed educational materials and counseling guidelines for patients and practitioners. They are participating in and monitoring a number of investigations, including VA studies of hepatitis C prevalence, an industry-sponsored study of treatment outcomes of combined therapy in veteran patients, and clinical studies of new drugs.

VA has developed cooperative outreach programs with Veterans Service Organizations, and private groups such as the American Liver Foundation, and the Hepatitis Foundation International. We are currently in the planning stages of the mailing of 4 million brochures, one to each enrolled veteran in VA.

The Acting Under Secretary for Health has released an additional \$20 million in reserve funds this fiscal year for hepatitis C initiatives. The amount provided each Network is proportional to their current fiscal year expenditures for this disease. In fiscal year 2001, we intend that the VERA funding will include recognition of the costs and the distribution of hepatitis C throughout VA and further adjustments will be made appropriately.

VA has also established a Web site that provides educational materials, guidelines, and information that has been presented at our various national clinical and counseling symposia.

Now, Mr. Chairman, with respect to the additional information sought by your staff, I will address those specific issues of interest.

From fiscal year 1998 throughout the first half of fiscal year 2000, approximately 325,000 veteran patients have been tested for hepatitis C. Approximately 65,000 have been found to be positive for those antibodies; that is about 20 percent of those tested.

You also asked about the number of veteran patients with hepatitis C who have received or are receiving treatment. This is difficult to determine precisely because there is no single data base that lists unique patients and drug treatment that is specific for

hepatitis C. The Pharmacy data base can identify from June 1999 individual patients on Rebetron or combined interferon/ribavirin, and hepatitis C is the only indication for that product. However, another treatment alternative is interferon alfa, and that drug is used to treat a number of diseases in addition to hepatitis C, for example, chronic myelogenous leukemia.

So in order to determine the total number of hepatitis C patients on either Rebetron or interferon alfa, we will have to compare patient lists by social security number across the pharmacy data base and the Emerging Pathogens Registry. This work is currently underway but is not yet completed. However, we do know, on the basis of these two data bases, the mean number of new patients started on Rebetron each month approximates 14 percent of the mean number of newly diagnosed hepatitis c patients each month, as reported in the Registry.

You asked what percentage of veterans with hepatitis C are eligible or appropriate for drug therapy. This is a question which we have been quite interested in, as you may imagine. The original estimates of our VA experts in liver disease were that about 20 percent of our patients would be eligible. Their estimates were based upon the observation that there are a number of absolute or relative contraindications to such therapy. The benefits, for example, often do not outweigh the risks for those with very mild liver disease or for advanced liver disease. Other contraindications include age greater than 60, significant extrahepatic disease, depression, autoimmune diseases, uncontrolled diabetes, moderate to severe anemia or low white cell or platelet counts, pregnancy or refusal to use contraception. The possibility of poor compliance with complex regimens must be considered. And finally, it is widely believed that ongoing alcohol or illicit drug use is an absolute indication.

As I have noted above, we have evidence that on average the number of new patients started on Rebetron each month represents about 14 percent of the total number of newly diagnosed patients each month. In addition, the San Francisco Center of Excellence has obtained risk factor and treatment candidacy information on veteran patients with hepatitis C at 26 medical centers across the country. Approximately 15 percent of the patients sampled were on treatment.

So we believe that when additional data are available in larger samples and the patients on interferon alfa alone are added to those on combination therapy the original 20 percent estimate will prove to have been reasonably close to the actual treatment rates that we are observing.

You asked when the direct comparisons of the Emerging Pathogens Registry and the Pharmacy data base would be complete. As stated, we have performed an initial match, but the two sources do not reflect the same period of time. We will attempt to select our patients from the same time interval in the two data bases. However, reducing the figures to a monthly average and comparing hepatitis C-positive patients with patients on treatment, an approach we have described above, the data suggests that the proportion on treatment with Rebetron, interferon alfa alone, or interferon alfa plus ribavirin is approximately 16 percent.



Mr. SHAYS. I am sorry, Dr. Holohan, we are going to have to go vote. We have three votes and you gentlemen need to get on your way. I do not know if you want to quickly get a bite to eat or something and we would come back in about 20 minutes.

Dr. HOLOHAN. Twenty minutes?

Mr. SHAYS. If we could be here at five after.

[Recess.]

Mr. SHAYS. Gentlemen, sorry to keep you waiting. I underestimated the time it would take to do three votes.

Dr. Holohan, if you would like to continue your statement. Thank you, and sorry to interrupt you.

Dr. HOLOHAN. Thank you, Mr. Chairman. I am not going to repeat what I have said except to again emphasize the numbers. We talked about the numbers that have been tested and that about 20 percent of the 325,000 tested have been positive. We talked about different mechanisms for looking at the data we have available to us about the percentage of positive patients who are treated, and those three different methodologies return 14, 15, and 16 percent respectively, which we believe is very similar to the predictions that some of our VA liver experts made several years ago about 20 percent of veteran patients who are positive being appropriate candidates for treatment.

The final statement, related to a question that your staff posed, was how the hepatitis C assessment reminder would be used, I think the phrase they used was "clinical reminder," and when it would be implemented. The way this system operates is that when a VA practitioner selects a patient's record for display, there is a computer program that automates the process of detecting and then excluding patients who have already been tested, whether they have positive or negative results, and it also excludes patients whose records indicate an established diagnosis of hepatitis C based on ICD-9 codes. So the clinician then knows whether the patient in question has already been tested, has an established diagnosis, or needs to be assessed for risk factors. If the latter situation obtains, presumably assessment then would be initiated.

The earliest version of this program was released to all sites in March of this year, 2000. The Information Office has informed us that an enhanced reminder program was distributed in June of this year. I believe the VA clinicians testifying here today will endorse the effectiveness of this assessment clinical reminder. And software currently under development will collect and provide more comprehensive data that will include other laboratory results, medication usage, and information related to status with regard to hepatitis A and hepatitis B for issues of coinfection.

That concludes my oral testimony, Mr. Chairman. I am pleased to answer any questions.

[The prepared statement of Dr. Holohan follows:]

Statement of  
Thomas V. Holohan, M.D.  
Chief Patient Care Services Officer  
Department of Veterans Affairs  
Before the  
Subcommittee on National Security, Veterans Affairs, And International Relations  
Committee on Government Reform  
U.S. House of Representatives

July 12, 2000

Mr. Chairman and members of the Subcommittee, I am pleased to appear before you today to discuss our ongoing efforts to address issues of Hepatitis C (HCV) in the veteran population receiving care through the Department of Veterans Affairs (VA). I am accompanied by Jimmy Norris, Chief Financial Officer for the Veterans Health Administration.

Since our last report to you in June, 1999, VA has achieved a number of goals in its attempt to establish an appropriate system-wide approach to the HCV problem. These efforts include better identification and treatment of HCV patients, expanded educational and counseling efforts, commencement of a multi-center research trial, collaborative outreach programs, and changes in funding allocation methodology in order to more accurately reflect the resources required by HCV treatment.

**The HCV Registry**

The Emerging Pathogens Index (EPI) registry is a computer program which automatically extracts information regarding each positive test for Hepatitis C virus antibody in the VA, and forwards that information to a central data base. Data in the Registry indicate that from FY 1998 through the second quarter of

this fiscal year, approximately 325,000 veterans have been tested; of that number, 65,000 unique veteran patients have been found to have HCV.

#### **Risk Factor Evaluation**

To encourage screening and to more accurately determine the number of veterans who are being evaluated for risk factors, formal clinical reminders are being added to the information base available to VA clinicians. Patients who have had a blood test for antibodies to HCV, or who have a diagnostic code (ICD-9 code) associated with HCV are considered to have been appropriately tested or diagnosed. Absent those criteria, a reminder notice for risk factor evaluation and possible testing appears on the computer screen. The enhancement is now in place, and preliminary evaluation is underway. In addition, a performance measure targeting the percentage of patients that should be screened over the next year is currently under development.

#### **Treatment**

The guidelines for treatment of HCV are under continual review, and are modified as new information is available. The most recent update was completed in January 2000 (Appendix 1).

Information from the Pharmacy Benefits Management database indicates that since July 1999, an average of 344 new patients are started on combination therapy with interferon-alpha and ribavirin (Rebetron) each month. This represents approximately 14 percent of newly diagnosed cases. The specific number of patients treated for HCV with interferon-alpha alone is not currently known but is under study. VA clinicians with specific expertise in HCV had estimated that about 20% of all HCV positive veteran patients might be appropriate candidates for treatment. We believe that the pharmacy database numbers, when complete, are likely to validate those initial estimates.

### **Centers of Excellence**

During the past year, the Centers of Excellence in Hepatitis C, located in San Francisco and Miami, have been involved in numerous important projects; these include:

- Completion and distribution of veteran-specific educational materials for the 22 Networks, Veterans Service Organizations, and VA's Vet Centers.
- Completion of counseling guidelines and a "Train the Trainer" educational seminar in March 2000. A second seminar is scheduled for September 2000.
- Continuation of a VHA Cooperative Studies Protocol to assess the prevalence of HCV in the veteran population.
- Implementation of an industry funded multi-center trial to determine a number of outcomes which include treatment response to combination therapy, assessment of those factors which affect disease progression, and detection of any differences in response rates attributable to race/ethnicity.
- Clinical research on new drugs for the treatment of HCV.
- Development of a model for use by Networks and facilities to help achieve consistency in the provision of care across the entire system.
- Preparation of a "telephone triage" booklet for use at all levels of the organization to answer patient questions and direct them to appropriate care.

### **Outreach Efforts**

VA has continued to collaborate with the American Liver Foundation, Hepatitis Foundation International and the Veterans Service Organizations. Patient testing programs were held during the months of March, April and early July. Presentations were made at the annual meeting of Hepatitis Foundation International, at several VSO national meetings and to VA's Council on Minority Veterans. VA also participated in the Public Service Awareness Week with a staffed booth on the mall featuring our efforts in HCV. The first meeting of the

American Liver Foundation's Veterans Council was held in June 2000, to discuss barriers to outreach and develop an action plan to overcome these barriers for veterans who are users of the traditional VA system of care and those who are not. Veteran-specific brochures have been prepared by a number of Networks, and similar efforts are being prepared on a national scale.

#### **Funding and Resources**

The Acting Under Secretary for Health has initiated the release of additional funding in FY 2000 for HCV and changes in the resource allocation formula that will begin in FY 2001. This fiscal year, an additional \$20 million from the national reserve fund will be distributed across the VISNs in proportion to their existing expenditures for HCV. While the distribution is based upon past resource use, it closely follows the HCV patient numbers by VISN, thus reflecting both actual and potential workload and resource utilization. (Appendix 2) Beginning in FY 2001, VERA funding will include recognition of the costs and distribution of HCV, thereby assuring appropriate funding both for patient care and geographic distribution of patients. At present, available information indicates that about 78% of HCV patients whose annual drug costs are at least \$5,000 are already reimbursed under VERA at the Complex care price.

#### **VA Web Site**

VHA has established a web site, accessible via the internet, to provide information on HCV. This includes patient and physician educational materials, evaluation and screening guidelines, treatment guidelines, treatment side effects, slide presentations from the Clinical and HCV Counseling Symposia, and links of interest. This can be accessed through the address: [www.va.gov/hepatitisc](http://www.va.gov/hepatitisc).

**Summary**

Mr. Chairman, VA continues to lead the nation in identification, counseling and treatment of patients with HCV. The release of \$20 million from the National Reserve account and adjustments to VERA for 2001 will support our VA health care facilities in addressing outreach, screening, diagnosis, and treatment for patients with HCV. While the prevalence and costs of HCV vary across the country, we will work to assure that a consistent level of screening, testing and access to treatment are available wherever the veteran receives care. We look forward to working with Congress to assure that the VA's care for HCV represents the best practice in the nation.

This concludes my statement. We will be pleased to respond to the Committee's questions.

## Appendix 1

### Treatment Guidelines

#### Background

HCV is a chronic viral infection which rarely remits spontaneously. Approximately 20% of patients develop cirrhosis, but the natural history of HCV disease is highly variable, with some patients progressing to cirrhosis in 15 years, and others never progressing to cirrhosis over a life-time (1). Treatments for HCV disease remain inadequate, since approximately 50% of patients will never achieve a sustained benefit from therapy, regardless of the dose and duration of administration. Interferon alfa and interferon alfa plus ribavirin are approved by the FDA for treatment "naïve" patients with HCV disease. However, interferon-based therapies must be administered parenterally, and have significant side effects. There are also a substantial number of patients in whom treatment is contraindicated. In view of the variability in natural history, the cost of treatment and the lack of uniform benefit, treatment should ideally be provided to those at greatest risk of progressive liver disease and to those in whom quality of life is reduced from chronic infection. The recommendations outlined below are based primarily on those put forward at the National Institutes of Health Development Conference in 1997 (2) and the CDC recommendations for the identification, counseling, testing and referral of persons at risk for HCV infection in 1998 (3). These recommendations have been updated since the recent FDA-approval of combination interferon plus ribavirin which occurred since the publication of these two documents.

#### Management

Management of patients who are anti-HCV positive by ELISA should include:

1. Education regarding factors such as alcohol use which increase the risk of progressive liver injury
2. Counseling on modes of transmission of HCV including parenteral and sexual transmission
3. Medical assessment regarding need for vaccination against hepatitis A and B
4. Evaluation for potential therapy

In order to determine need for therapy, anti-HCV positive persons should be assessed for:

- confirmation of diagnosis (see V.A. screening guidelines for HCV)
- biochemical evidence of chronic liver disease by serum alanine aminotransferase (ALT) and serum aspartate transaminase (AST)

- severity of disease and possible treatment according to current practice guidelines in consultation with, or referral to, a specialist knowledgeable in this area. Liver biopsy although not essential, is strongly recommended
- adequate hemoglobin, white blood cell and platelet counts to tolerate therapy
- measurement of hepatic synthetic function (serum albumin, bilirubin, prothrombin time)
- determination of potential contraindications to therapy (table 1)

## **FDA-approved treatments**

### **Treatment naive patients**

#### **Combination therapy**

The FDA approved the combination of interferon and the oral antiviral agent ribavirin (Rebetron R) for initial treatment of chronic hepatitis C. The results of multicenter randomized controlled trials in the United States and Europe (4,5) have shown significant benefit with combination therapy versus monotherapy. The sustained virological response six months off therapy in patients receiving 48 weeks of therapy was 38 per cent compared with 13 per cent in those receiving interferon monotherapy for 48 weeks. In the whole population, 48 weeks of combination therapy was significantly better than 24 weeks (31 per cent). As with interferon monotherapy, there was a strong influence of genotype on response. Sustained virological response in patients with the most common genotype in the U.S., genotype 1, was 29 per cent, while response in non-1 genotypes was 66 per cent. Patients with genotype 1 infection benefited from 48 versus 24 weeks of combination therapy (28 and 16 per cent respectively). In contrast, there was no additional benefit of 48 versus 24 weeks of therapy in patients with non-1 infection.

As a result of these trials, combination therapy appears to be the treatment of choice for naive patients. However, if there are contraindications to the use of ribavirin such as patients with unstable cardiac disease, those with anemia or those who might conceive on treatment or within six months of completion of therapy, the patient should be treated with interferon monotherapy (6).

#### **Monotherapy**

For patients who are not candidates for combination therapy, other FDA-approved treatments for those who are "treatment naive" include three formulations of interferon (interferon alfa 2a, interferon alfa 2b and interferon alfa con-1). Doses range from 3MU three times weekly for 12-18 months (for interferon alfa 2a, interferon alfa 2b) to 9 mg three times weekly for interferon alfa con-1. Large-scale studies have demonstrated the benefit of increased duration of therapy to 12 months in reducing relapse rates (6).



**Previously treated patients**

Both combination treatment and interferon monotherapy are FDA-approved for the treatment of "relapsed" patients - those who have previously received interferon, responded biochemically on therapy but then subsequently failed to maintain a normal serum ALT when treatment was stopped (7,8). Response rates in "relapsed" patients to combination therapy for 6 months and to interferon alfa con-1 monotherapy (15 mg three times weekly) for 12 months are similar with either therapy (7,8).

**Definition of response**

Efficacy of treatment is measured biochemically (defined as normalization of serum ALT) virologically (defined as undetectable serum HCV RNA) and histologically (defined as reduction in liver inflammation and/or fibrosis on post-treatment liver biopsy). Because of concordance between improvement in liver histology and biochemical and virological response in the majority of patients, post-treatment liver biopsy is not routinely recommended. Treatment end-points are measured at two time-points - end-of-treatment (ETR) and 6 months post-treatment (sustained response or SR).

**Response to treatment**

With interferon monotherapy at standard doses, biochemical ETR at 12 months is observed in 30-40 per cent and biochemical SR in 15-20 per cent of cases (5,6,8). With the same regimen, virological ETR is 20-30 per cent and virological SR is 10-15 per cent (5,8). Biochemical and virological improvement is typically associated with histological improvement. The addition of ribavirin at doses of 1,000-1,200 mg to interferon at standard doses for 12 months increases the virological SR to approximately 40 per cent (5).

In patients who have previously been treated with interferon without initial normalization of serum ALT and/or loss of HCV RNA, further interferon with or without ribavirin is only occasionally associated (< 10 per cent) with prolonged benefit and is currently rarely indicated in clinical practice. However, in patients who have been treated with interferon and have had a biochemical and virological ETR but not SR (transient responders or relapsers), retreatment with interferons such as interferon alfa con-1 (15 mg three times weekly for 48 weeks) or interferon in combination with ribavirin can result in a virological SR of 40-50 per cent (7,8).

While these studies are encouraging, the benefits of treatment on important clinical outcomes such as quality of life and disease progression remain to be determined.

**Selection of patients for treatment**

All patients with chronic hepatitis C are potential candidates for therapy. However, given the current limitations of therapies, treatment is clearly recommended only in a selected group of patients. In others, treatment decisions are less clear and should be made on an individual basis or in the context of clinical trials.

**Treatment is clearly indicated for the following group:**

**Patients with histologically moderate disease**

The NIH Consensus Development Conference determined that treatment is recommended for patients with chronic hepatitis C who are at greatest risk for progression to cirrhosis. These are patients with persistently abnormal serum ALT, detectable serum HCV RNA by sensitive assays and liver histology showing fibrosis with or without moderate inflammation and necrosis.

Information published since the NIH Consensus Conference suggests that equal response rates are achievable in patients with significant fibrosis including cirrhosis as in those without fibrosis (4,5). Thus patients with compensated cirrhosis should be considered appropriate candidates for therapy.

**Treatment is less clearly indicated in:**

**Patients with histologically mild disease**

Therapy is less clearly indicated in patients with mild liver disease in which there is Grade 1 inflammation and no evidence of fibrosis since the rate of progression to cirrhosis is slow, and indeed these patients may never develop advanced liver disease. In these patients, therapy may be undertaken, since this is the group of patients that has the greatest chance of viral clearance with treatment. Alternately, the patient and the physician may elect to observe without treatment, and periodically measure serum ALT with repeat liver biopsy in 3-5 years to determine if disease is progressive.

**Patients with normal serum ALT**

Therapy is not indicated in those patients with persistently normal serum ALT. Normal ALT does not preclude histological evidence of liver injury, but interferon treatment, even in patients who are viremic, rarely results in viral clearance, and may lead to elevations of serum ALT. No data are available regarding the use of interferon/ribavirin in patients with normal ALT. Treatment of such individuals should be in the setting of a clinical trial.

**Patients with histologically advanced disease**

Patients with cirrhosis and clinical complications of liver disease (gastroesophageal bleeding, ascites, encephalopathy, impaired hepatic synthetic function etc.) typically respond poorly to treatment and may even be at risk for further hepatic decompensation on interferon. Thus patients with clinically decompensated cirrhosis should not be treated with interferon and should be referred for consideration of liver transplantation.

**Patients over the age of 60 or those with significant non-hepatic disease**

Given the long interval between infection and the development of complications of liver disease and the variability in the natural history of infection, in patients who are over the age of 60 years or who have significant disease other than liver disease - for example symptomatic coronary artery disease, uncontrolled diabetes, renal insufficiency, symptomatic chronic obstructive pulmonary disease - treatment is not routinely indicated. In these individuals, the life expectancy of the underlying condition should be taken into account when discussing the potential benefits of treatment. Patients who have undergone solid organ transplantation should be treated with caution because of a theoretical risk of precipitating allograft rejection. Given the inadequacy of data regarding

treatment recommendations in these groups, whenever possible, these patients should be treated in the context of therapeutic trials.

### **Pre-treatment assessments**

(see table 2)

1. All patients must have documentation of anti-HCV positivity, confirmed when the diagnosis is in doubt by a recombinant immunoblot assay.
2. All patients should have a careful medical history and a physical examination to assess for symptoms and signs of chronic liver disease.
3. All patients must have elevated serum ALT but the duration and degree of elevation is not specified. Repeat ALT testing is also recommended at intervals in those with initially normal ALT since subsequent elevation would prompt further assessment.
4. Other common causes of liver disease such as alcoholic liver disease, active hepatitis B infection, hemochromatosis and autoimmune liver disease should be excluded.
5. Patients should have evidence of preserved hepatic synthetic function as indicated by a normal or near normal serum albumin, direct serum bilirubin and prothrombin time. Patients must also have a platelet count  $> 75 \text{ k/mm}^3$  and absolute neutrophil count  $> 1.5 \text{ k/mm}^3$  in order to tolerate therapy.
6. Testing for HCV RNA level (viral load) by a quantitative assay (quantitative PCR (qPCR) or branched DNA signal amplification assay (bDNA)) can provide information regarding the viral titer and may help counsel patients as to their likelihood of response. Patients with low viral load are more likely to respond to treatment than those with high viral load. However, there is no absolute predictor of response or non-response based on HCV RNA titer. Pre-treatment HCV RNA levels are optional but highly recommended.
7. There are at least six genotypes of HCV and more than 30 subtypes. There is extensive information that the genotype responsible for infection influences the response to interferon and likely also to interferon/ribavirin, with patients infected with genotype 1 consistently showing lower response rates than those infected with genotype non-1. However, there is currently no FDA-approved method for either genotyping or serotyping. While these tests are considered as research tools, they are increasingly being used in clinical practice. Recent studies suggest using 12 months of therapy for genotype 1 versus 6 months for genotype 2 or 3. Therefore for cost-effective management, assessing the HCV genotype, when available, is strongly recommended prior to therapy.
8. Because interferon can aggravate underlying autoimmune disorders, patients must be euthyroid (on replacement therapy if necessary) and their

diabetes, if present, must be controlled. Patients should also be assessed for coexistent autoimmune liver disease with a serum ANA, and if present in high titer, treatment should be administered with caution.

9. Serological markers of prior HBV and HAV infection should determine whether vaccination against HBV and/or HAV infection is appropriate.
10. Pregnancy test for women of child-bearing age considering interferon
11. Patients must undergo a careful evaluation for a history of depression or uncontrolled psychiatric disorders, they must be assessed for an adequate home environment for storage of interferon and they must be assessed for substance abuse. Ongoing alcohol use is an absolute contraindication since cessation of alcohol is considered to be of prime benefit to the liver disease. Ongoing injection drug use or other illicit drug use is also considered an absolute contraindication because of issues of compliance and need for patients to demonstrate their commitment to their treatment regimen. A past history of depression which has resolved or ongoing depression which is adequately controlled with therapy is not a contraindication to treatment but such patients should be managed in conjunction with a mental health professional.
12. Liver biopsy is considered the gold standard for assessment of patients with chronic hepatitis and is most useful for determining the severity of liver injury (i.e. the fibrosis stage of disease) (1). Liver biopsy may be helpful in excluding other causes of liver disease although this can be accomplished with reasonable accuracy by a careful history, physical examination and appropriate laboratory testing.

#### **Monitoring while on therapy**

1. Hemoglobin, hematocrit, white blood cell count, differential and platelet count should be monitored at week 1, week 2, week 4 and at periodic intervals (approximately monthly) during therapy. Particular attention must be paid to changes in hemoglobin in patients receiving interferon/ribavirin therapy.
2. Patients should be evaluated by a healthcare provider at 1-2 month intervals for side effects of therapy, and for guidance to manage these side effects.
3. Serum ALT should be monitored approximately monthly when the patient is undergoing phlebotomy for other tests.
4. In the patient receiving interferon monotherapy, HCV RNA should be tested at 3 months and a decision made regarding further therapy as discussed below. In the treatment naive patient with genotype 1 infection receiving combination therapy, HCV RNA should be tested at 6 months when a decision for further treatment is made. In the treatment naive

patient with non-1 infection or the relapse patient receiving combination therapy, treatment should be for 6 months regardless of biochemical or virological response so that HCV RNA results are not as critical for management. In all patients, HCV RNA measurement at the end of therapy and six months following therapy is useful to determine response or non-response and the durability of this response.

5. Thyroid function should be checked every 6 months.
6. Patients, male and female, should practice adequate contraception while on therapy, particularly if receiving interferon/ribavirin. Male patients should have barrier contraceptives issued on a monthly basis and female patients should have serum pregnancy tests done monthly. The only exception to this is surgical sterility of greater than one year.
7. Repeat liver biopsy outside a research protocol is rarely necessary to monitor response.
8. Guidelines for dose modifications of interferon/ribavirin include reduction of rebetol to 600mg daily for hemoglobin < 10g/dL for patients with a cardiac history, or for > 2 g/dL drop in hemoglobin over a four week period in all patients; interferon should be reduced to 1.5 MU tiw for WBC < 1.5, neutrophils < 0.75 or platelets less than 50k. Permanent discontinuation of both medications should occur for hemoglobin < 8.5 g/dL, WBC < 1.0, neutrophils < 0.5, platelets < 25k. For other guidelines, see product insert.

## **Current recommendations for treatment**

### **Treatment naive patients**

Interferon 3MU tiw and ribavirin (1,000 mg for <75 kg, 1,200 mg for > 75 kg in two divided doses daily) with a decision to continue or withdraw therapy based on biochemical and virological response at 6 months. Therapy should be continued if HCV RNA is negative and if serum ALT is normal for an additional 6 months in patients with genotype 1 infection. In those with genotype 2 or 3 infection, therapy should be only for 6 months regardless of virological or biochemical response.

Recommendations for management are less clear in the patient with either a biochemical or a virological response but not both. In general, the practice is to give a patient with one but not both markers of response the benefit of the doubt and to continue therapy.

### **Treatment naive patients with contraindications to ribavirin**

Interferon at FDA approved doses (3MU tiw for alfa 2a and alfa 2b, 9 mg for alfa con-1) for three months (12 weeks) with decision at 3 months to continue or withdraw therapy based on biochemical and/or virologic response.

If serum ALT is normal and/or HCV RNA is undetectable by a PCR-based assay at 3 months, treatment should be continued for a total of 48 weeks. If the serum ALT is abnormal and the HCV RNA is still detectable at 3 months, treatment should be discontinued.

Recommendations for management are less clear in the patient with either a biochemical or a virological response but not both. In general, the practice is to give such a patient the benefit of the doubt and to continue therapy.

**Interferon transient responders**

Retreatment with interferon/ribavirin (1,000-1,200 mg of ribavirin po qd plus interferon alfa 2b 3 MU tiw) for six months,  
or

Retreatment with 12 months of interferon (interferon alfa 2a, alfa 2b, alfa con-1) at standard doses or increased doses

Patients on monotherapy should be assessed with a qualitative PCR for HCV RNA at 3 months. If negative, treatment should be continued for a total course of 48 weeks. Discontinue therapy if patient at 3 months remains positive.

Patients on combination therapy should be treated for 6 months only regardless of genotype and regardless of response.

**Transient responders to combination therapy (interferon plus ribavirin)**

Retreatment with interferon alfa con-1 (15mg tiw) for 48 weeks can be considered in patients who have previously failed to respond or who have previously failed to tolerate a prior course of interferon, but response rates in patients previously treated with combination therapy are unknown (8).

Treatment within an experimental protocol is preferable.

**Non-responders to interferon monotherapy or to interferon/ribavirin combination therapy**

Retreatment with interferon alfa con-1 (15mg tiw) for 48 weeks can be considered in patients who have previously failed to respond or who have previously failed to tolerate a prior course of interferon, but response rates are low (approximately 10%) (8).

Treatment within an experimental protocol is preferable.

## **Concluding Comments:**

This outline represents recommendations for treatment based on currently available information and on treatment regimens that are currently FDA-approved. Because of ongoing research activity, treatment recommendations will need to be modified on a regular basis as new information becomes available. As response rates to treatment improve, new recommendations will be made.

Therapy should be provided to those individuals who are at greatest risk for progressive liver disease and to those individuals whose quality of life is most likely to improve after therapy. At the same time, clinical research must include testing of hepatitis therapies in the populations who are infected, since extrapolation of results obtained in the highly selected populations who are included in clinical trials to the general veteran population is potentially problematic.

Optimization of these goals will require clinical and basic research to enhance the treatments that we provide, as well as clinical research to determine the natural history and morbidity resulting from this chronic viral disease.

**References:**

1. Poynard T, Bedossa P, Opolon P for the OBSVIRC, METAVIR, CLINIVIR and DOSVIRC groups. Natural history of liver fibrosis progression in patients with chronic hepatitis C. *Lancet* 1997;349:825-832.
2. National Institutes of Health Consensus Development Conference Panel Statement: Management of Hepatitis C. *Hepatology* 1997;26 (Suppl 1):2S-10S.
3. CDC Recommendations for the identification, counseling, testing and referral of persons at risk for hepatitis C virus (HCV) infection.
4. Poynard T, Marcellin P, Lee SS et al. Randomised trial of interferon alpha 2b plus ribavirin for 48 weeks or for 24 weeks versus interferon alpha 2b plus placebo for 48 weeks for treatment of chronic infection with hepatitis C virus. International Hepatitis Interventional Therapy Group (IHIT). *Lancet* 1998;352:1426-32.
5. McHutchison JG, Gordon SC, Schiff ER et al. Interferon alfa-2b alone or in combination with ribavirin as initial treatment for chronic hepatitis C. *N Engl J Med* 1998;339:1485-92.
6. Poynard T, Bedossa P, Chevalier M. A comparison of three interferon alfa-2b regimens for the long-term treatment of chronic non-A, non-B hepatitis. *N Engl J Med* 1995;332:1457-1462.
7. Davis GL, Esteban-Mur R, Rustgi V, Hoefs J, Gordon S, Trepo C et al. Interferon alfa-2b alone or in combination with ribavirin for the treatment of relapse of chronic hepatitis C. *N Engl J Med* 1998;339:1493-99.
8. Keeffe EB, Hollinger FB and the Consensus Interferon Study Group. *Hepatology* 1997;26:101S-107S.
9. Reichard O, Norkrans G, Fryden A, Braconier J-H, Sonnerborg A, Weiland O et al. Randomized, double-blind, placebo-controlled trial of interferon a-2b with and without ribavirin for chronic hepatitis C. *Lancet* 1998;351:83-87.

<b>Table 1. Contraindications to HCV therapy</b>	
1.	Non-compliance with medications and clinic visits
2.	Life-determining extrahepatic disease (e.g. unstable angina, severe COPD)
3.	Moderate or severe psychiatric disease particularly depression uncontrolled by medication or suicidal ideation
4.	Recent or ongoing illicit drug use
5.	Ongoing alcohol use (more than 1 drink per day)
6.	Clinically decompensated liver disease
7.	Inadequate social support for self administration of parenteral medication
8.	Pregnancy
9.	Uncontrolled autoimmune disorders
10.	Failure to use adequate birth control for males or females during treatment



<b>Table 2: Pre-treatment assessments in a patient with chronic HCV</b>	
1.	Anti-HCV positive by ELISA (confirmed by RIBA if diagnosis is in doubt) (necessary)
2.	Medical history including determination of complications of liver disease, significant extrahepatic disease and symptoms associated with chronic HCV which may reduce quality of life (necessary)
3.	Psychiatric and social history including determination of past or ongoing substance abuse, assessment of concomitant depression or post-traumatic stress disorder (necessary)
4.	Biochemical markers of liver injury and assessment of hepatic synthetic function (serum ALT, serum albumin, serum bilirubin (particularly direct bilirubin), prothrombin time) (necessary)
5.	Hemoglobin, hematocrit, total white cell count, differential and platelet count (necessary)
6.	TSH, serum glucose (necessary)
7.	Pregnancy test (necessary for women of child-bearing potential)
8.	Serum ferritin, HBsAg, markers of autoimmune liver disease (necessary)
9.	HCV RNA level by qPCR or bDNA (optional but highly recommended)
10.	HCV genotype or serotype (necessary for interferon/ribavirin)
11.	HBsAg, anti-HBcAb (total), anti-HBsAb, anti-HAV total
12.	Liver biopsy to stage severity of liver disease (optional but highly recommended)

Guidelines for dose modifications

	Dose Reduction REBETOL - 600 mg daily INTRON A - 1.5 million IU TIW	Permanent Discontinuation of Treatment REBETOL and INTRON A
Hemoglobin	<10 g/dL (REBETOL) Cardiac History Patients Only. $\geq$ g/dL decrease during any 4-week period during treatment (REBETOL/INTRON A)	<8.5 g/dL Cardiac History Patients Only. < 12 g/dL after 4 weeks of dose reduction.
White blood count	<1.5 x 10 <sup>9</sup> /L (INTRON A)	<1.0 x 10 <sup>9</sup> /L
Neutrophil count	<0.75 x 10 <sup>9</sup> /L (INTRON A)	<0.5 x 10 <sup>9</sup> /L
Platelet count	<50 x 10 <sup>9</sup> /L (INTRON A)	<25 x 10 <sup>9</sup> /L

## Appendix 2 --FY 2000 Supplemental Funding for Hepatitis C

	Network	Qtrs 1 & 2 FY 00		% of Total Hep C Expenditures	Allocation from Reserve of \$20 mil*
		Expenditures	Hep C		
1	Boston	\$1,179,683		3.01%	\$602,500
2	Albany	\$559,408		1.43%	\$285,707
3	Bronx	\$3,582,922		9.10%	\$1,819,693
4	Pittsburgh	\$1,827,787		4.67%	\$933,507
5	Baltimore	\$1,000,607		2.56%	\$511,041
6	Durham	\$1,563,446		3.99%	\$798,500
7	Atlanta	\$1,910,445		4.88%	\$975,723
8	Bay Pines	\$3,252,571		8.31%	\$1,661,188
9	Nashville	\$2,374,422		6.06%	\$1,212,690
10	Cincinnati	\$1,403,089		3.58%	\$716,601
11	Ann Arbor	\$1,230,560		3.14%	\$628,485
12	Chicago	\$1,525,181		3.89%	\$778,957
13	Minneapolis	\$682,374		1.74%	\$348,509
14	Omaha	\$769,885		1.97%	\$393,204
15	Kansas City	\$1,457,782		3.72%	\$744,534
16	Jackson	\$3,029,116		7.74%	\$1,547,062
17	Dallas	\$1,829,502		4.67%	\$934,383
18	Phoenix	\$1,671,903		4.27%	\$853,892
19	Denver	\$1,363,934		3.48%	\$696,603
20	Portland	\$1,967,489		5.02%	\$1,004,857
21	San Francisco	\$2,451,535		6.26%	\$1,252,074
22	Long Beach	\$2,545,946		6.50%	\$1,300,293
	National Totals	\$39,159,587		100.00%	\$20,000,000

Allocations are based on the VISN percentage of Hepatitis C expenditures for the first six months of FY 2000

Mr. SHAYS. Thank you, Dr. Holohan.  
We will now go to Dr. Ho.

**STATEMENT OF DR. SAMUEL B. HO, M.D., STAFF PHYSICIAN,  
MINNEAPOLIS VA MEDICAL CENTER**

Dr. HO. Chairman Shays and members of the committee, thank you for this invitation to speak regarding hepatitis C: access, testing, and treatment. I have been the supervising gastroenterologist for the hepatitis C clinic at the Minneapolis VA Medical Center for the past 10 years. I have worked closely with our administrators in our Veterans Integrated Service Network [VISN 13] over the last 3 years to develop a comprehensive health care product line for hepatitis C diagnosis and treatment. Over that period of time, I have learned much from my patients with hepatitis C, and I appreciate the comments of Mr. Baker, Mr. Bryant, and Mr. Lesinski. I would like to tell you about my experience with one patient because it illustrates the challenges and opportunities that we face.

Mr. B was referred to our clinic 2 years ago because he was diagnosed with hepatitis C through his primary care clinic. He had served in the Army and was stationed in South Vietnam in 1971. He was hit during a rocket attack, which blew off his left lower leg and partially destroyed his right calf. He was most likely infected with hepatitis C after receiving a blood transfusion during surgery when they had to amputate his left leg.

He never experienced symptoms from hepatitis C until 3 years ago, 26 years after being infected. The symptom that he developed was incapacitating fatigue, and he was found to have cirrhosis, or severe scarring of the liver, after undergoing a liver biopsy.

We treated him with a new treatment, a combination of two drugs, interferon and ribavirin, which was available to us at that time only on an experimental basis. This drug therapy lasted 1 year and required visits to our clinic every 2 to 4 weeks for blood test monitoring. The treatment, as the others have testified, was not easy for him. He developed severe headaches and worsening phantom leg pain requiring narcotics. He also experienced a worsening of his previous depression problem, which required additional therapy from our psychiatrists. He was, however, able to finish 1 year of therapy. Since then, I am happy to say, he has had normal liver enzyme tests and all tests for hepatitis C virus have been negative. We consider him to be cured from this infection.

He feels much better and tells me he has been out golfing quite frequently now. Recent publications indicate that his cirrhosis may actually start regressing, and that his risks for the need of a liver transplant and/or treatment for liver cancer are markedly reduced.

This patient I believe is typical of our patients. One, he was a Vietnam veteran who has carried the virus for 25 to 30 years and typically was without symptoms until he developed severe liver disease. This has largely been the reason why many of these patients have gone unrecognized until relatively recently. Of the last 200 liver biopsies we have done at our institution on veterans referred for hepatitis C treatment, we have found that 33 percent had pre-cirrhosis or cirrhosis, which I believe is a greater degree of severity than others are finding in the general population of hepatitis C. Third, he had a pre-existing, psychiatric diagnosis. Again, in our

last 200 patients referred for treatment, we found that 50 percent of our patients with hepatitis C experienced greater problems and need more care in order to get them through the hepatitis C treatment, and 50 percent have these established psychiatric diagnoses that make their treatment much more complicated. Last, he illustrates the fact that within the last 2 years we have had improved therapies for hepatitis C and that it appears that we can cure 40 percent of patients who are able to receive this therapy.

Mr. Chairman, we realized that, due to the long duration of infection in most of our patients and their current burden of disease, we had a narrowing window of opportunity to identify and treat our patients before it was too late. Further improvements in hepatitis C therapies that are becoming apparent on the horizon have been compelling us with an increasing degree of urgency to find and treat as many of these patients as possible. We were convinced that a greater investment in resources now would help us reduce the tragedy and expense of complications of end-stage liver disease due to hepatitis C that we face over the next two decades. I was pleased that the administration of the VA health care system here in Washington has provided such strong leadership on these issues and has come to these same conclusions over the last 2 years that I did in my institution.

The VA Upper Midwest Health Care Network (VISN 13) consists of six medical facilities serving approximately 97,000 patients in portions of seven States. There is one tertiary care medical center located in Minneapolis. Our initial screening study indicated that we may have as many as 5,000 patients with hepatitis C in our VISN patient population. Again, over the last 2 years, we have worked to try and address many of the issues that have been brought up today in establishing a VISN-wide program for the diagnosis and management of these obviously complex patients.

To summarize, the five key elements of the plan that we have come up with include: One, to initiate standard hepatitis C screening procedures for all primary care and specialty care clinics. We have been assisted in this by the automated "clinical reminder" system, that Dr. Holohan just mentioned, for identifying and recording patients who need hepatitis C screening. Since our system began last February, we have been screening 1,143 patients per month.

Two, for hepatitis C-positive patients, we have standard education, evaluation, and referral protocols performed by personnel in primary care clinics or by the hepatitis clinic.

Three, we have a centralized VISN 13 Chronic Hepatitis C Clinic in Minneapolis to provide specialty care by gastroenterologists and infectious disease physicians to evaluate eligible patients and initiate treatment according to the VA treatment guidelines. Again, since how we understand hepatitis C and its treatment is continually changing, the role of specialists will continue to be important in guiding what we do for these patients.

Four, we are establishing hepatitis care teams at each VISN medical center to provide hepatitis C chemotherapies and assist in all aspects of screening and diagnosis.

Five, we have a centralized outcome monitoring system and coordination of patients being offered treatment using investigational

protocols. Ongoing research at VA medical centers continues to be critical for improving therapies for patients with hepatitis C and many other diseases.

The details of this plan have been published in the Veterans Health System Journal, and more details are outlined in my written statement.

In my experience, the most important element of this plan is the establishment of a hepatitis C care team at each medical center. And the most important part of this team is a full-time nurse level position which would be responsible for coordination of screening tests, patient notification, patient education, and patient monitoring during therapy. Again, we have found it very important to involve a psychologist or psychiatrist at each medical center, since 50 percent of our patients with hepatitis C have established psychiatric diagnoses such as post-traumatic stress disorder or depression.

Mr. Chairman, this really is a new disease for the VA with new and expensive treatments that are difficult to administer. I believe that the key elements outlined above will provide the foundation for VISN 13 to provide quality care for veteran patients with hepatitis C and I hope may serve as a model for other VISNs in the VA health care system.

Thank you very much for this opportunity to testify.

[The prepared statement of Dr. Ho follows:]

Statement of  
 Dr. Samuel B. Ho  
 VA Medical Center, Minneapolis, MN  
 Before the  
 Subcommittee on National Security, Veterans  
 Affairs and International Relations  
 July 12, 2000

Mr. Chairman and members of the committee thank you for the invitation to speak regarding hepatitis C: Access, Testing and Treatment in the VA Health Care System. I have been the supervising Gastroenterologist for the hepatitis C clinic at the Minneapolis VA Medical Center for the past 10 years. I have worked closely with our administrators in our Veterans Integrated Service Network (VISN 13), over the last three years to develop a comprehensive health care "product line" for hepatitis C diagnosis and treatment.

My work in the chronic hepatitis clinic involves taking care of patients, such as Mr. B, who was referred to our clinic two years ago because he was diagnosed with hepatitis C. Mr. B served in the Army and was stationed in South Vietnam in 1971. He was hit during a rocket attack, which blew off his left lower leg and partially destroyed his right calf muscle. He was most likely infected with hepatitis C after receiving a blood transfusion during surgery when they had to amputate his left leg because of these wounds. He never experienced symptoms from hepatitis C until three years ago, 26 years after being infected. The symptom that Mr. B developed included incapacitating fatigue and he was found to have cirrhosis, or severe scarring of the liver, after undergoing a liver biopsy. We treated Mr. B with a new treatment, the combination of two drugs, interferon-alpha and ribavirin, which was available to us at the time only on an experimental basis. This drug therapy lasted one year and required visits to our clinic every two to four weeks for blood test monitoring. The treatment was not easy for him. He developed severe headaches and worsening phantom leg pain requiring narcotic drug therapy. He also experienced a worsening of his previous depression problem, which required additional therapy from our psychiatrists. Mr. B was able to finish one year of therapy. Since then, he has had normal liver enzyme tests and all tests for hepatitis C virus have been negative. We consider him to be cured from this infection. He feels much better and tells me he has been out golfing

quite frequently. Recent publications indicate that his cirrhosis may actually start regressing, and his risks for need of a liver transplant and/or treatment for liver cancer are markedly reduced.

Recent studies have indicated that hepatitis C is more common in veteran patients than in the general population. Mr. B is typical of our veteran patients with hepatitis C. Most are Vietnam-era veterans who may have contracted the infection in the late 1960's and 1970's. Unlike those with hepatitis C in the general population, veterans were at increased risk for hepatitis C due to exposure to other people's blood or tissues during combat or military service-related duties, or blood transfusions related to combat injuries. Research by Dr. Theresa Wright's group at the San Francisco VA, has indicated that combat-related blood exposures is a statistically significant risk factor that is independent of the other usual risk factors. For example, I have one patient who was an ambulance driver at a military base in the United States who never used plastic gloves while taking care of patients, at that time this practice was not as common as it is today. I have another patient who was injured in a land mine incident when his buddy stepped on a mine and part of his buddy's femur ended up in my patient's left leg. The most common risk factor in veterans and the general population is the use of intravenous drugs, which occurred, in epidemic proportions among young men and women in the late 1960's and 1970's. It may be for these reasons that hepatitis C is found more commonly among veteran patients than the general population.

Mr. B is also typical in that early on there are very few symptoms from this infection until severe liver damage has evolved. Recent research has given us a much clearer picture of the natural history of this infection. The data indicates that approximately 70-80% of adults who are initially infected with this virus will end up with a persistent infection; and that it takes an average of 33 years before the scarring in the liver develops to the point of being cirrhosis. Being a male and the use of alcohol accelerates this scarring process; and perhaps veterans with hepatitis C have a greater degree of liver injury compared with other patients. We have recently reviewed the last 200 liver biopsies of veterans referred for hepatitis C treatment at our institution, and have found that 33% have pre-cirrhosis (or stage 3-4 fibrosis). Patients with cirrhosis of the liver are at much greater risk for developing liver failure and or liver cancer, and we can expect these patients to succumb to this at a rate of about 20% over 4 years. This will result in a great deal of illness and suffering among our veteran patients and a considerable health care burden that will increasingly impact on the



resources of the VA. Dr. Gary Davis, and colleagues at the University of Florida, Gainesville, have conservatively estimated that for the nation as a whole, over the next 10 years we can expect a 61% increase in cirrhosis, a 279% increase in patients with liver failure symptoms, a 68% increase in liver cancer, a 528% increase in the need for liver transplants and a 223% increase in liver-related deaths.

Two years ago, we were fortunate to have an experimental therapy to treat Mr. B. Later in 1998, FDA approved this drug therapy, interferon-alpha and ribavirin, for general use. Large clinical studies in the United State and Europe indicate that this therapy can cure approximately 40% of patients who are able to receive it. It is possible that the FDA may approve a new therapy next year, a drug called pegylated-interferon, which in combination with ribavirin may allow us to cure 50% of patients with chronic hepatitis C. Data from Dr. Sobesky and colleagues in France and Dr. Shiratori and colleagues in Japan indicate that once the hepatitis C virus is eliminated, the scarring or fibrosis that developed in the liver will begin to regress over time. They also found that even if the virus was not eliminated, the progression of liver scarring was slowed in those patients that received treatment.

Mr. Chairman, due to the long duration of infection in most of our patients and their current burden of disease, we have a narrowing window of opportunity to identify and treat our patients before complications that are more serious develop. Further improvements in hepatitis C therapies that are on the horizon compel us with an increasing degree of urgency to diagnose and treat as many of these patients as possible. I am convinced that a greater investment in resources now will help us to reduce the tragedy and expense of the complications of end-stage liver disease due to hepatitis C that we face over the next two decades.

The VA Upper Midwest Health Care Network (VISN 13) consists of six medical facilities serving approximately 97,000 patients in portions of seven states. There is one tertiary care medical center located in Minneapolis, Minnesota. Our initial screening study indicated that we may have as many as 5,000 patients with hepatitis C in our VISN patient population. Over the last two years, we have worked to establish a VISN-wide program for the diagnosis and management of patients with hepatitis C.

The five key elements of this care plan for VISN 13 are as follows:

- Standard HCV screening procedures for all primary care and specialty care clinics. We have initiated an automated "clinical reminders" system for identifying and recording patients who need hepatitis C screening.
- Standard education, evaluation, and referral protocol provided by personnel in primary care clinics or by hepatitis clinics. Referral criteria for further care require that patients be educated about hepatitis C and meet criteria for treatment eligibility.
- Centralized VISN 13 chronic hepatitis C in Minneapolis, Minnesota to evaluate eligible patients and initiate treatment according to standardized VA treatment guidelines.
- Completion of hepatitis C chemotherapy by "hepatitis care teams" at each VISN medical center according to an established protocol.
- Centralized outcome monitoring and coordination of patients being treated using investigational protocols. Ongoing research at VA medical centers continues to be critical for improving therapies for patients with hepatitis C and many other diseases.

The details of this plan have been published in Veterans Health Care System Journal and are outlined in the addendum below. In my experience, the most important element of this plan is the establishment of a "hepatitis C care team" at each medical center. The most important part of this team is a full time nurse, nurse practitioner, or physician assistant, who is responsible for coordination of screening tests, patient notification, patient education, and patient monitoring during therapy. The number of additional staff depends on the estimated numbers of patients with hepatitis C in a particular center. A physician is required to help supervise the evaluation and initiation of treatment. We have found it very important to involve a psychologist or psychiatrist at each medical center, since 50% of our patients with hepatitis C have established psychiatric diagnoses, such as post-traumatic stress disorder or depression. This is important because the therapies for hepatitis C often exacerbate these conditions. Tertiary centers with specialists in gastroenterology and/or infectious disease are responsible for providing the evaluations and consultations regarding therapy by establishing a Chronic Hepatitis Clinic. Again, we have found that a nurse practitioner working with a gastroenterologist is very efficient.

The Chronic Hepatitis Clinic we established in Minneapolis VAMC consists of a single nurse practitioner working under my supervision. This clinic has the capacity to see 35 patients total per week and averaged 20 new patients per month (including 75% local patients and 25% referrals from other medical centers in the VISN). We have evaluated 200 new patients with hepatitis C in the first year and started about 90 patients on chemotherapy during this time. Since our automated "clinical reminders" screening system went into effect in the primary care clinic in February 2000, we have screened 1,143 new patients each month for hepatitis C risk factors and have ordered 1,489 hepatitis C antibody tests between February and June of this year. We are adding two full time positions to this clinic, one nursing position to manage the screening and education of our patients and one additional nurse practitioner to enable us to double the number of patients we treat.

We have responsibility for 97,000 patients in our VISN. My experience with this plan indicates that the VISN will ultimately need to assign a total of 8 full time nursing positions and two physicians for the hepatitis C screening and care program in the VISN. Additional nominal investment in clinic and office space may also be necessary. We are currently able to treat 33% of hepatitis C patients, and I estimate that as many as 1,600 patients may be eligible for treatment. The pharmacy cost of therapy at the current time is almost \$1,000 per month and treatment lasts from 6 – 12 months. These factors, in a nutshell, account for the majority of hepatitis C care costs in our VISN, and I believe the minimum infrastructure needed to provide necessary care. As experience increases and increased screening efforts bring in more patients, we may need to increase this infrastructure in the future.

Mr. Chairman, this is a new disease for the VA, with new and expensive treatments that are difficult to administer.

In summary, my clinical experience and recent medical literature all support the need for a very aggressive effort to diagnose and treat as many patients with hepatitis C as we can in order to reduce the immense personal and financial costs of the consequences of hepatitis C infection that we know will occur over the next two decades. I believe that the "key elements" outlined above will provide the foundation for VISN 13 to provide quality care for veteran patients with hepatitis C. As experience with this care system accumulates, we may need to make adjustments in the resources devoted to patients with hepatitis C.

Thank you very much for this opportunity to testify.

## ADDENDUM TO TESTIMONY

Dr. Samuel B. Ho  
Minneapolis, MN VAMC  
July 12, 2000

Key elements of hepatitis C care in VISN 13:

1. Providers and patients should be aware of the risk factors for hepatitis. We recommend that patient with risk factors for hepatitis C be offered testing with hepatitis C ELISA with subsequent documentation of the results. Once a patient with a positive hepatitis C antibody is identified, they require education, evaluation, and possible referral. We recommend that each medical center identify one or more health care professionals to coordinate screening procedures and initial patient's education and evaluation. In most cases a confirmatory hepatitis C test should be obtained, which most often consists of a hepatitis C (HCV) PCR test in our clinic (alternatively some centers use HCV RIBA test). This is most important for the patient in who there is a question about the diagnosis; i.e., if they have normal liver enzymes, a questionable risk factor, or if they have autoimmune conditions, that can cause a false positive ELISA test.
2. Patient education regarding hepatitis C is a critical element, and should occur in the patient's primary care clinic. Education should include general facts about the disease, how to prevent its spread, and how to reduce the possible progression of disease (such as discontinuation of alcohol use). At the same time patients receive this education, they should be informed of the possible treatments available for hepatitis C and the requirements for receiving this treatment. We recommend that the criteria for referral of a patient with hepatitis C to a gastroenterology or other subspecialty clinic for treatment should include the following: before beginning treatment. The patient must have no ongoing active illicit drug or alcohol use (must demonstrate at least six months of abstinence), no active psychiatric disease, no active medical problems with expected mortality (malignancy, severe heart or lung disease, etc.) and the patient must have an interest in receiving medical treatment. We use a pre-printed outpatient record form for assisting with patient education and referral. This includes a checklist of education points and a checklist of referral criteria. Patients not meeting referral criteria should be

- periodically re-evaluated, offered psychiatric or chemical dependency treatment if appropriate, and referred when criteria are met.
3. The medical evaluation prior to initiation of treatment is important in order to determine duration of treatment and the nature and extent of other diseases that may impact on the safety of the patient during treatment. This evaluation is done by practitioners in the Chronic Hepatitis Clinic at the Minneapolis VAMC and includes:
    - ◆ Confirmation of diagnosis with biochemical and virological evidence of chronic disease. This would include determination of HCV genotype and a qualitative viral blood level.
    - ◆ Exclusion of other common causes of liver disease as clinically indicated.
    - ◆ Liver biopsy to determine grade and stage of liver disease (recommended by not mandatory)
    - ◆ Baseline labs that are consistent with set standards prior to treatment
    - ◆ Assessment regarding vaccination against hepatitis A and hepatitis B
    - ◆ Review of possible contraindications to therapy by evaluation of related medical, psychosocial, illicit drug and alcohol use issues. We require formal psychiatric evaluation and follow-up prior to initiating treatment in a patient with a prior history of major depression and other psychiatric diseases.
  4. As outlined above, current data indicated that alpha-2b interferon plus ribavirin is first line therapy. Treatment guidelines will continue to evolve, as more data becomes available. We currently recommend treatment of patients with genotype 1 for an initial 24 weeks. If they have responded to therapy at that time with not measurable HCV RNA in the serum, they would continue therapy for another 24 weeks. If they have measurable serum HCV RNA at 24 weeks, treatment would be stopped. We recommend that patients with HCV genotypes 2 or 3, low viral blood levels or with mild fibrosis on liver biopsy receive therapy for a total of 24 weeks, and then therapy is stopped. Current guidelines do not recommend therapy for patients with hepatitis C, positive HCV RNA, and persistently normal liver function tests. We recommend following these patients with liver function tests yearly. Recommendations for this group of patients may change in the future as more knowledge concerning their natural history becomes available. Once treatment is initiated, patients require close follow-up, laboratory monitoring, and supervision according to established protocols. After a

patient has started therapy with interferon alpha and ribavirin, the "hepatitis C care teams" can follow them at their referring medical centers. These teams consist of one or more primary care physicians and nurses who have an interest in hepatitis C and are willing to work with the specialists at our centralized Chronic Hepatitis Clinic.

5. An important component of this treatment program will be to monitor treatment outcomes. A database will be maintained on all VISN patients in order to evaluate numbers of patients, severity of disease, and rate of sustained response to therapies. It is well recognized that efficacy in clinical trials often is different from effectiveness in clinical practice. Given the great expense and potential morbidity of current hepatitis C treatments, accurate information on the effectiveness of these treatments in our patient population will be useful for ongoing decisions regarding resource needs and the cost-benefits of providing these therapies. In addition, patients should be offered participation in investigational protocols to insure that continued progress in care for Hepatitis C is made.

Mr. SHAYS. Thank you, Dr. Ho.  
Dr. Brau.

**STATEMENT OF DR. NORBERT BRAU, M.D., STAFF PHYSICIAN,  
BRONX VA MEDICAL CENTER**

Dr. BRAU. Mr. Chairman, members of the subcommittee, I would like to thank you for inviting me to speak before the subcommittee on how VISN Network 3 meets the challenge of hepatitis C. I am an infectious disease physician at the Bronx VA medical center where I am also the director of the Viral Hepatitis Clinic, and I am the founder and co-chair of the VISN 3 Hepatitis C Task Force.

As you all know, infection with hepatitis C virus [HCV] does become chronic in 75 percent of infected individuals, and chronic hepatitis C can lead to liver cirrhosis and liver cancer. Today, it is the most common cause for liver transplantation in this country. Combination therapy with interferon and ribavirin can cure the chronic infection and then the liver disease in about 38 percent of the patients.

U.S. veterans are much more commonly afflicted with hepatitis C than the general population. A VA-wide study from March 1999 revealed that 6.6 percent of U.S. veterans have been infected compared to 1.8 percent of the general population. The prevalence is much higher in networks with a large number of urban centers, like the Washington, DC area, New York City, or southern California.

Veterans Integrated Service Network 3 is comprised of five VA medical centers in the New York City metropolitan area. Our network has the highest prevalence of hepatitis C, based on that survey, amongst all networks, with 13 percent. Two of the five VA medical centers rank among the top five VA hospitals nationwide in terms of the hepatitis C rates. In addition, we conducted a study in network 3 where we found that amongst the HCV-positive veterans there is a substantial rate of coinfection with HIV-I of 21 percent which further complicates the matter.

Based on the VA survey, we estimate that there are currently about 11,000 veterans receiving care in network 3 who are infected with hepatitis C virus that do not know it because typically the disease does not cause any symptoms. Therefore, network 3 has started a program of actively identifying all infected veterans by actively reaching out to veterans who might be at-risk but do not know that they are infected.

The way that we do it is that every veteran who attends a primary care clinic will receive a hepatitis C risk screen based on the number of risk factors, and every veteran who has one or more risk factors will be tested for hepatitis C. The Computerized Patient Record System, which I think is probably one of the best clinical software systems anywhere, helps the clinician do the screening by putting in clinical reminders, as it was mentioned.

A patient who tests HCV-positive is then referred to a specialty clinic. These specialty clinics are usually run by either infectious disease physicians or gastroenterologist or hepatology specialists. After referral to such a clinic, the veteran will typically be counselled by a social worker or nurse on the impact of the disease, possible modes of transmission to family members, on alcohol abstinence.

nence, and vaccinations, and also information brochures will be handed out to the veterans. Then a specialty physician will do a thorough evaluation of that veteran and also have a thorough discussion on the pros and cons of treatment, and where possible, the patient will be put on treatments. Also, we will invite veterans, where appropriate, to participate in clinical research studies.

The care of hepatitis C-positive veterans in network 3 is coordinated by the hepatitis C network 3 task force which meets monthly by teleconference. We started our work in July of last year. Since our inception, we have achieved a number of goals: One, we centralized all the molecular testing, including viral load and genotyping, at the Bronx VA microbiology lab, which also was the first lab in the VA system that introduced the HCV genotyping.

Two, we are coordinating research studies within our network, including the one with HIV coinfection and another one with genotype distribution.

Three, we have established an ongoing systematic collection of data on both risk factor screening, testing, and treatment of veterans.

Based on this data base, we have learned that just in the first 4 months of systematic screening with the help of the clinical reminders for risk factors, the primary care clinicians in network 3 have already screened 22 percent of all veterans that receive care there. Of those who were screened, 29 percent had a risk factor for hepatitis C or had already tested positive. Over the last 1½ years, 21,000 veterans at risk were tested for hepatitis C virus, and 27 percent tested positive.

As a result of the intensive screening and referral of hepatitis C-positive veterans, the number of veterans who received treatment for chronic hepatitis C in network 3 is growing. In all of fiscal year 1999, we treated 383 veterans. In the first three-quarters of fiscal year 2000, which just finished in June of this year, we treated 365 veterans for hepatitis C, which represents an increase of 27 percent over the same time period of last year.

Now as we already heard, not all veterans with chronic hepatitis C are candidates for treatment. About 25 percent of those who have chronic viremia, meaning the virus is detectable, or 15 percent of those who have the antibody will ultimately be put on treatment. The main reasons for not treating patients for hepatitis C include: the patient is reluctant to receive treatment, she/he has minimal liver disease, or there are serious medical or psychiatric illnesses that would represent a contraindication to treatment with ribavirin and interferon.

Taking care of veterans and treating them for hepatitis C is labor-intensive and requires expensive tests and treatments. VA Central Office has estimated that it costs approximately \$20,000 to put one veteran through a course of treatment. And this estimate does not include a possible second course of treatment that may be necessary when the first one fails.

Until now, hepatitis C care in network 3 has continued at a very high level of quality regardless of funding issues. In fact, every single hospital director in our network has been extremely supportive of the ongoing and growing care of hepatitis C treatment, even though it does strain their budgets. Already, waiting times for a re-



ferral to the hepatitis specialty clinics averages 2 months, and reaches up to 4 months in some centers, although we would like to keep it less than 4 weeks.

As the number of veterans who are identified with hepatitis C is growing, additional staffing and funding for drugs and laboratory tests will be required. One of the promising ideas that is currently being discussed in VA Central Office would be to follow the example of HIV treatment, whereby veterans who are receiving treatment for hepatitis C would be put under specialty care category and each medical center, through its network, would receive special funding for that treatment.

Mr. Chairman, in summary, an effort by dedicated professionals can buildup a systematic program of reaching out for veterans, testing them, and treating them for hepatitis C. Given the proper support, this effort can be sustained even as the growing number of veterans are referred.

[The prepared statement of Dr. Brau follows:]



DEPARTMENT OF VETERANS AFFAIRS  
Medical Center  
130 West Kingsbridge Road  
Bronx, New York 10468

**Statement of  
Norbert Bräu, M.D.  
Bronx Veterans Affairs Medical Center  
Regarding  
Hepatitis C: Access, Testing and  
Treatment in the VA Health Care System  
Before the  
Subcommittee on National Security,  
Veterans Affairs, and International Relations  
Committee on Government Reform  
U. S. House of Representatives**

July 12, 2000

Mr. Chairman, Members of Congress:

Infection with the hepatitis C virus (HCV) becomes chronic in 75% of infected individuals. Chronic hepatitis C can lead to liver cirrhosis and liver cancer, and today it is the most common indication for liver transplantation in the United States. Combination treatment with interferon and ribavirin given over 12 months can cure chronic hepatitis C in 38% of patients in whom progressive liver disease is then averted.

U.S. veterans are more commonly afflicted with hepatitis C than non-veterans. A VA-wide survey on March 17, 1999, revealed that 6.6% of veterans who use VA and who had testing on that day have been infected with HCV compared to 1.8% in the general population (CDC data). It is estimated that about 90,000 U.S. veterans have chronic hepatitis C (i.e. virus is detectable in the blood) and need to be evaluated for treatment. Hepatitis C in veterans is more prevalent in regions with large urban areas, like New York City (13%) Southern California (9%) or Washington D.C. (8%).

Veterans Integrated Service Network 3 (VISN 3) has the highest rate of hepatitis C of all VA networks with 13%. VISN 3 is comprised of five VAMCs in the New York City metropolitan area. Two of them rank in the top five hepatitis C rates among 138 VAMCs nationwide: New York VAMC with 18% and Bronx VAMC with 16%. Furthermore, a study in VISN 3 has shown that its patients are more commonly infected with HCV genotype 1 which has a lower response rate to treatment: 88% genotype 1 among veterans compared to 75% in the general population. Also HCV(+) veterans in VISN 3 have a very high rate (21%) of co-infection with HIV.

Based on the VA survey, it is estimated that about 11,000 veterans who receive care in VISN 3, are chronically infected with HCV. Many of them do not know yet that they have chronic hepatitis C, because the infection typically does not cause symptoms. Medical care for HCV(+) veterans in the network is coordinated by the VISN 3 Hepatitis C Task Force. This task force meets monthly and is comprised of hepatitis C specialty physicians (infectious diseases, gastroenterology) and nurses from each VAMC. The hepatitis C task force began its work in July 1999 and has since then accomplished a series of goals: (1) Centralization of all hepatitis C

molecular tests like viral load or genotype in one reference laboratory at the Bronx VAMC. The Bronx VA microbiology lab was the first lab in the VA system to introduce HCV genotyping. (2) Ongoing systematic data collection on risk screening, testing and treatment through the VISTA computer system. This now allows for rapid real-time data presentation in response to inquiries from Congress or VA Central Office. (3) Coordination of network-wide research on hepatitis C, including a recent study on HCV genotyping and co-infection with HIV. In 1999, VISN 3 began a campaign of identifying all veterans with chronic hepatitis C by actively reaching out for veterans who might be infected but have no symptoms. In the primary care clinics, every veteran who receives care is being screened for HCV risk factors; and, if one or more are present, an HCV antibody test will be done. The Computerized Patient Record System (CPRS) helps physicians in their screening activity by automatically putting clinical reminders into each patient's medical record.

All veterans who test positive are referred to a hepatitis C specialty clinic, run by infectious diseases/gastroenterology/hepatology specialists. In the specialty clinic, the HCV(+) patient receives intensive counseling by a nurse or social worker on the significance and prognosis of the disease, on possible transmission of the virus, alcohol abstinence and vaccinations and will be provided with up-to-date educational material to read. The specialty physician performs a thorough evaluation, discusses pros and cons of treatment with the patient, and starts treatment where appropriate. Patients on treatment are followed closely for possible side effects and complications by physicians, nurses, social workers and clinical pharmacists who work together as an interdisciplinary team. Where appropriate, patients may be invited to participate in a clinical research study.

In the first three months of systematic HCV risk screening, physicians in VISN 3 have already assessed 22% of all vested veterans. About 29% of the screened patients are at risk for hepatitis C or already tested positive. In the last 1½ years, 21,000 veterans at risk were tested for HCV, and 27% tested positive. The number of veterans who receive treatment for chronic hepatitis C in VISN 3 is growing: 383 patients in all of FY 1999 and 365 in the first three quarters of FY 2000, a 27% increase over the same period in FY 1999. Of all veterans with chronic hepatitis C, about 25% will ultimately be treated. The main reasons for not treating are: patient's reluctance, minimal liver disease, or serious medical and psychiatric conditions in which treatment with interferon and ribavirin is contraindicated.

Caring for patients with hepatitis C requires plenty of resources. VA Central Office has estimated that it costs \$20,000 to treat a patient for hepatitis C. This estimate does not account for patients who require a second course of treatment because the first one failed.

Until now, hepatitis C care in VISN 3 has continued at a high level of quality regardless of funding issues. All hospital directors have been extremely supportive of the active and growing treatment of HCV(+) veterans, even though it strains their budgets. Waiting times for an appointment in the hepatitis C clinics average two months now (in some clinics, up to four months), and they are getting longer. As a growing number of veterans with chronic hepatitis C are identified, additional staffing and funding for drugs and laboratory tests will be required.

**Norbert Bräu, M.D.**

CoChair, VISN 3 Hepatitis C Task Force  
Medical Director, Viral Hepatitis Clinic  
Infectious Diseases Physician  
Bronx VA Medical Center

Mr. SHAYS. Thank you, Dr. Brau.  
Dr. Iber.

**STATEMENT OF DR. FRANK IBER, M.D., HEPATOLOGIST,  
VOLUNTEER AT HINES VA MEDICAL CENTER, HINES, IL**

Dr. IBER. Chairman Shays and members of the subcommittee, I am a trained liver expert who has taught and done liver research in medical schools for nearly 50 years including 25 years in the VA medical system, most recently at the Hines VA Hospital in Chicago. I am now retired but continue to work 1 day a week treating veterans with hepatitis C.

When interferon therapy was shown effective for hepatitis C in 1995–1996, I started a program at Hines treating all appropriate veterans. In the next 2 years, we treated 60 patients, representing about one-third of our patients then recognized with hepatitis C. Of those who started treatment, some 90 percent stayed on treatment for the required 6 months.

Treatment requires close supervision, as you have heard from many, because there are unknowing and life-threatening complications. Frequent visits, laboratory tests, special systems must be created to accommodate these patients in order to keep their cooperation in treatment. Over time, an effective treatment program was established using the machinery already present at our hospital.

After 18 months of supervising the HCV program, I retired for reasons of age. I was not replaced with another liver doctor because of budgetary restrictions and our administration did not recognize the need for a specialist. The followup of patients was left to primary care doctors who usually had only one HCV patient under treatment.

Four months after my departure, only one-tenth of the patients requiring treatment remained on their drugs. The supervising physicians often stopped medications due to limited familiarity with possible toxicity, and the patients stopped medication because they could not obtain prompt evaluation.

After 5 months of retirement, I returned to Hines as a volunteer 1 day each week to supervise the HCV treatment program. My primary focus is counseling patients before they start treatment, advising and reviewing results of treatment and side effects, reassuring many patients who are frightened or discouraged about continuing treatment. Our VAMC has identified more and more veterans who have hepatitis C.

However, the harsh reality is that the numbers identified, now almost 450 patients, have overwhelmed our system for evaluating and following these patients. This inundation has led to delays of 4 to 6 months in initiating treatment, of fewer identified patients being admitted to treatment, and failure to keep patients on treatment. All of these problems exist because there are just too few doctors and nurses assigned to the hepatitis C program.

In my experience, special needs of hepatitis C treatments are present, and many of them have already been pointed out. You need access to a physician experienced with hepatitis C; you need an integration in an expedited fashion of lab, pharmacy, consultants, particularly psychiatry; you need a full-time professional coor-

dinator, usually a nurse; and you need a committed administration. Currently, all of these elements are not yet in place in our VA hospital even though we have treated more than 200 patients.

Let me elaborate on these unique needs. An experienced hepatitis C physician is needed because only 8 percent of VA patients meet every nuance of the current VA guidelines for treatment, yet at least a third, and maybe even more presenting patients will benefit from treatment. Determination of which details are important require experience and training. Upon completion of current treatment, two-thirds of the patients, not the veterans we heard here today who were success stories, but the majority still have the infection and these veterans want and even demand informed information on what they should do next. This requires special help.

Second, an expedited system. Interview and laboratory testing must be performed at least monthly. Drugs cannot be provided until these safety checks are completed. About 1 in 10 of our visits require consultation with another type of doctor to evaluate the severity of side effects. The four-fifths of our current patients who have no extra problems complete all of this in a single monthly visit of 1 hour's duration, and this allows people to continue a full-time job. If the ordinary clinic procedure were followed, a minimum of three visits, taking at least 6 hours, would be required to accomplish the same thing.

And finally, you need a nurse or other professional to supervise, interfacing when the unexpected occurs, and assuring the patients at all times.

What can Congress do to help? I think that we have already heard some of these things are approaching being in place, but I think every health unit should report not only the new hepatitis C patients identified, but those entered into treatment in the same time and those who have a cure. Because if we put in the cure, this will provide a superb scorecard of how well each unit is doing.

Second, and I think others have mentioned this, hepatitis C, like HIV, is a disease that requires a lot of resources to manage. It should be reimbursed as a complicated disease, certainly not a simple one.

Every facility should have access to the elements of a hepatitis C evaluation, as presented by Dr. Ho, and treatment. This, whenever possible, should be onsite, but sometimes it will be necessary for it to be in a nearby VA facility or even purchased through civilian outlets through the consultation process.

And it is my opinion that every facility that has at least 10 patients under treatment with HCV should have a full-time professional assigned priority to manage these patients and that this should be specifically funded centrally so that the money cannot be used for other things, to make sure that such a person is available at every site.

Thank you very much for your attention.

[The prepared statement of Dr. Iber follows:]

90

STATEMENT OF

Frank Iber, MD

COMMITTEE ON GOVERNMENT REFORM

SUBCOMMITTEE ON NATIONAL SECURITY, VETERANS  
AFFAIRS AND INTERNATIONAL RELATIONS

HEPATITIS C:  
ACCESS, TESTING and TREATMENT  
IN THE VA HEALTH CARE SYSTEM

JULY 12, 2000

Dear Chairman Shays and Members of the Subcommittee:

Thank you for this opportunity to speak about my professional experiences with Hepatitis C.

I am a trained liver expert who has taught and done liver research in medical schools for nearly 50 years including 25 years with the VA. I worked at the Hines VA Medical Center in Chicago, Illinois for 14 years as a hepatologist. I am now retired, but continue to work one day a week treating veterans with hepatitis C.

When interferon therapy became an effective treatment for hepatitis C in 1996, I started a program at Hines VAMC treating all appropriate veterans. In the next two years, we treated some 60 patients, representing about one-third of our HCV patients. Of those who started treatment, some 90 percent completed the required 6 months on drug.

Treatment requires close coordination between nursing, laboratory, pharmacy, psychiatrists and the primary treating physician because the drug has many minor and some major side effects. These side effects often require laboratory and complaint monitoring which in turn results in consultations and reassurances to help patients remain in treatment. A flexible schedule is essential in order for working people to undergo treatment and preserve their livelihood simultaneously. We are proud that nearly half our patients held full-time jobs

while undergoing treatment. At our hospital, a functioning, coordinated system was achieved through the voluntary assistance from many, including industry initially donating drugs and lab tests, the laboratory providing results in an expedited manner, and many professionals giving extra care to these hepatitis C patients. A patient-friendly system was created by bending many rules and former methods of treatment. Only after we were able to demonstrate a successful, working program were we supported by the administration.

After 18 months of supervising the HCV program at the Hines VAMC, I retired for reasons of age. I was not replaced with another liver doctor because of budgetary restrictions and the administration did not recognize the need for a specialist to supervise the treatment of HCV infection. The follow-up of patients was left to their primary care doctors who were most often residents in internal medicine. Four months after my departure, only ten percent of the patients requiring treatment remained on their drugs. The supervising physicians often stopped medication due to possible toxicity and the patients stopped medication because they could not obtain prompt evaluation and reassurance that they should continue.

After five months of retirement, I returned to Hines as a volunteer for one day each week to supervise the HCV treatment program. My primary focus is counseling patients before they start treatment, advising and reviewing results of treatment and side effects and, reassuring many patients who are frightened or



discouraged about whether they are doing the correct thing in continuing treatment. Ribavirin has since become available and essentially all new patients are started on combination therapy.

As part of an overall VA thrust, the Hines VAMC has a clear effort to identify and treat more and more veterans who have hepatitis C. However, the harsh reality is that the numbers identified (almost 450 patients with HCV) have overwhelmed our system for evaluating and following these patients. This inundation has led to delays of between 4 to 6 months in initiating treatment and denial of treatment to patients with problems such as previous psychosis or substance abuse that would almost certainly require substantial professional attention if treatment were started. The infrastructure needed to evaluate, advise and treat the volume of veterans presenting with hepatitis C is simply not there.

In my experience there are unique needs (somewhat similar to those for AIDS or HIV infection) associated with the effective treatment of hepatitis C. These unique needs are: 1) an experienced physician in hepatology and hepatitis C to clearly determine which patients are in fact eligible for treatment and to maintain them in treatment; 2) an integrated and expedited system involving the lab, the pharmacy, and psychiatry with 3) a full-time, available professional decision maker to coordinate and transmit a learned view to the patient; and, 4) an administration committed to the same goal of providing quality care and treatment to veterans with HCV. Currently, all of these elements are not yet in

place at our VA hospital even though we are reputed to have treated the most patients at one VAMC in the US, now over 200 veterans have at least started treatment. Happily, I believe that all of these elements will be in place by the end of this calendar year.

Let me elaborate on these unique needs. First, concerning an experienced physician in hepatology and hepatitis C, available at least weekly (a consultant is a possible solution). Current guidelines for treatment are met completely by only about 8 percent of VA patients, yet at least 35 to 50 percent of presenting patients will benefit from HCV treatment. So, experience is needed in determining which details may be overlooked to start treatment. Upon completion of two drug therapies currently, 60 percent of patients still have the infection and these veterans want accurate information on what they should do next. A problem facing the VA is the inadequate salary – nearly \$30,000 less than in the private sector – being offered to recruit full-time trained liver doctors. The VA simply cannot compete for qualified physicians in this field.

Second, an integrated and expedited system. Interview and laboratory testing must be performed at least monthly, drugs cannot be provided until these safety checks are completed, about 1 out of every 10 visits require a consultation to evaluate the severity of side effects. All patients have a variety of side effects that require prompt, compassionate evaluation to continue on treatment. Many patients are able to complete all of this in a single monthly visit, approximately

one hour in length with a follow-up phone call. If the ordinary clinic procedure were followed, a minimum of three visits would be required to accomplish the same thing. Furthermore, for employed patients, we can complete their visit as early as 6:30 a.m. or as late as 7 p.m. confirming that it is okay to continue treatment.

Third, a full-time nurse, nurse practitioner, physicians assistant or physician assigned to supervise all of these patients is essential to coordinate all of these activities, intervene when the unexpected occurs, and reassure the patients and their families. We have found that such a person supplemented by the information services provided around the clock by interferon manufacturers and emergency rooms meets the patients' needs.

Fourth, an administration committed to supplying these resources for hepatitis C patients without merging hepatitis C treatment with all of the other challenges of VA medical care is necessary. In the evolution of our program, it has been necessary, at various stages in the past, to beg free drugs from the manufacturer, to obtain expensive laboratory tests such as genotype and viral loads privately and it remains difficult to obtain indicated treatment for those who have failed in their initial two drug trials. As national guidelines have emerged, these difficulties are being resolved but ever so slowly.

Possible solutions to improve access and treatment to veterans with HCV in the VA health care system:

- 1) Create a bonus structure directly linked to the annual reporting of the number of new veterans identified with HCV, those entered into treatment, and those who have a "cure" six months after the treatment is finished. This will provide a scorecard to compare one center and program with another.
- 2) Hepatitis C, like HIV, is a disease that requires a lot of resources to manage. It should be reimbursed as a complicated disease, not a simple one to provide appropriate reimbursement to the centers undertaking the treatment.
- 3) Every facility should have access to the elements of hepatitis C evaluation and treatment. This can be onsite or purchased through consultation, but it must be mandated to be present.
- 4) Every facility with at least 10 patients under HCV treatment should have a full-time nurse, nurse practitioner, physicians assistant, or physician assigned primarily to manage these patients. Funds should be provided separately for the employment of this person to strongly motivate the centers to do this. With training nurses or nurse practitioners can supervise a treatment program and can work within each clinic or center to assure effective treatment.

Clearly the need and desire for effective treatment among veterans exists. The VA health care system even has most of the elements available except for the commitment to their efficient blending into acceptable treatment in a single visit. As a VA physician who continues to witness the results of a disjointed, inconsistent approach to treating this disease, I would appreciate this Committee involvement in assisting the VA to finally implement a HCV program that provides quality HCV care to all veterans.

Thank you for your time and attention.

Frank Iber, MD  
339 Selbourne Road  
Riverside, IL 60546

Mr. SHAYS. Thank you very much, Dr. Iber.

Mr. Snyder, you are going to have the floor, then I am going to take it, and then I may have to leave, but I will let you come back and ask some questions afterwards as well, and then you can just adjourn the committee. So why don't you start.

Mr. SNYDER. You all heard the testimony by our veterans this morning and some of them had some fairly strong worded statements to make about some of the evaluation and treatment processes that they saw. Dr. Iber, in your written statement, and I think you said it also, "the harsh reality is that the numbers identified have overwhelmed our system," and then you say, "The infrastructure needed to evaluate, advise and treat the volume of veterans presenting with hepatitis C is simply not there." That is a pretty confirmatory statement of what our veterans said this morning.

Dr. Holohan, do you agree with that?

Dr. HOLOHAN. I have no evidence to disagree with that.

Mr. SNYDER. So that we currently have a VA system overwhelmed with numbers and more is to come?

Dr. HOLOHAN. I think it is probably premature to say the entire system is overwhelmed with numbers. I think that some of the testimony you heard today indicate that people are working hard but they seem to be able to meet the challenges. I would be naive, and you would consider me dissembling, to say that I thought that was the case throughout the country.

Mr. SNYDER. In terms of specifics, Dr. Holohan, is this a problem of money, a problem of just catching up with a relatively new disease entity? Where do you see we are in this? I have a lot of praise for the VA in terms of over the last decade I think you all have been ahead of the curve most of the time in terms of research and trying to get a handle on it. But it is obvious there are some problems from your own statement just a moment ago.

Dr. HOLOHAN. Right. I think probably all of the factors that you mentioned obtain. No. 1 is the absolute number of veteran patients that will require evaluation and treatment is large. The systems that existed did not exist to meet that demand. So I think there are going to be inevitable bottlenecks. I think the issue of funding was probably raised by the VA several years ago when we requested additional funding for hepatitis C initiatives. One of the problems is in terms of the specialists. It is a lot easier to take money from your wallet today and buy drugs than it is to take the same amount of money and find a hepatologist willing and able to work in VA. So I think it is a number of those things that are happening at the same time.

Mr. SNYDER. Are there statutory things getting in your way?

Dr. HOLOHAN. Not to my knowledge, sir.

Mr. SNYDER. Pay scales for hepatologists, is that statutory or is that something you all set?

Dr. HOLOHAN. Those are reviewed. I will have to defer, but I think those pay scale issues are reviewed on a routine basis every 4 years, and it is coming up again. But in my experience, and it is not limited to hepatologists, the pay scales are issues for many, many, many specialties—interventional radiologists, anesthesiologists, etc.

Mr. SNYDER. One of you had somewhere in your written statement I think it was a \$30,000 figure. Was that you, Dr. Iber?

Dr. IBER. Yes, sir.

Mr. SNYDER. Which is less than what you would get in the private world.

Dr. HOLOHAN, what is your assessment of the current status of the screening aspects of things. Dr. Iber's statement is that we do not have the infrastructure to evaluate and advise. Do you agree with that also?

Dr. HOLOHAN. Not entirely. I alluded to the automated clinical reminder system, which was put into effect because we came to believe that the response to the Under Secretary for Health's information letter in 1997 that listed risk factors that each veteran patient was to be quizzed about, and I am sure you have seen the document, we did not seem to be getting the kind of response that we had hoped. So it was decided that we would spend the time, effort, and money to develop an automated risk assessment reminder system.

The information I have been given from both the Chief Information Officer and from our clinicians, some of whom mentioned it in their testimony, is that it appears to be pretty effective as a screening and evaluation tool. So I am not quite as critical as I might have been in the past before this was instituted.

Mr. SNYDER. I had one specific question, Dr. Holohan. You quoted a 20 percent figure, 65,000 out of 325,000 I believe.

Dr. HOLOHAN. Right.

Mr. SNYDER. Which is substantially higher than the national "dip stick" day.

Dr. HOLOHAN. Correct.

Mr. SNYDER. I guess what you are saying that this is just not a typical population?

Dr. HOLOHAN. Actually, the percentage positive out of all tests done has been diminishing over time. My suspicion when we first began to get the data from Dr. Roselle's Registry was that people were not actually being "screened" simply on the basis of risk factors. What was happening was most tests were being done because the clinician suspected the patient had liver disease for some other reason. The initial data we got in the first year of the Registry was that 30 percent of all patients screened were positive, and that is very high. That indicates to me that they were not routinely following the risk factor list and screening on that basis, they were using more compelling information. But that has dropped to 20 percent now. It probably should be a little lower than that, I am not sure how much lower. But I think the change indicates that there is more screening than testing for cause.

Mr. SNYDER. Let me see if I understand what you are saying. Are you saying that if people are following your screening procedures, you are going to have some of your risk factors that are lower risk factors but they need to be tested also.

Dr. HOLOHAN. Correct.

Mr. SNYDER. And if all of them are tested, a substantial number of them are not going to be positives and so you should have a higher negative rate than you think you have right now. Is that correct?

Dr. HOLOHAN. That is my belief, yes, sir.

Mr. SNYDER. I understand. There was some criticism earlier by our panel of veterans about the treatment protocols. With regard to the treatment of patients that are treated in the VA system, is the treatment that you begin on individual veterans and the protocols that you follow, is that the same as would be found in a non-veteran hospital, in a civilian hospital, or has it been modified?

Dr. HOLOHAN. I will defer to the clinicians. But the first thing I would say is I am not sure what most civilian hospitals use. There are no systems that have provided that. I disagree very much with a statement made by one of the earlier panelists that our guidelines are wrong and need revision. I do not believe that is the case. I think the people who put that together are among the top liver experts in the country. But I will defer to our active clinicians as to the treatment guidelines.

Dr. HO. I think the VA treatment guidelines are pretty much exactly as what is being followed in the community. They are largely based on the NIH consensus statement which now is a couple years old. These guidelines are just guidelines, and we are getting new data everyday and so there is some evolution of those guidelines. There is one area of people who have normal liver function tests that is highly controversial among the experts right now and that still is evolving. The current VA and NIH guidelines call for perhaps not treating those patients. But I consider that is one area that will continue to evolve and we will have to wait for the experts. But at the current time, I am very satisfied with the VA guidelines and believe it is the same as in the community.

Dr. BRAU. I would think that in the VA the veterans with hepatitis C receive the same good care that they would receive anywhere else in the civilian world. The treatments are changing and things like the liver enzymes and whether one should treat by liver enzymes or by liver biopsy is being discussed and is controversial in the hepatitis C community. But typically the experts who treat the veterans do go to those international conferences where they do hear the latest opinion on that and keep themselves up to date.

Mr. SHAYS. I thank the gentleman. We will go back to you later. Before I have to leave at 1, I would like to ask a few questions. They relate to the conceptual issue of two Centers of Excellence and a whole number of other facilities that are not so-called centers of excellence. I do not understand the concept, and you will understand why when I ask the question later. But maybe you could explain the concept to me, Dr. Holohan.

Dr. HOLOHAN. I am actually glad you brought that up. The impression that I got from previous discussions is that the view of the two Centers of Excellence is that they are designated as centers of clinical excellence for the treatment of hepatitis C. And such is not the case.

Those two centers were selected and are centrally funded for their work, not centrally funded for clinical care, in two areas. One is educational production and distribution of educational and informational materials, counseling, and so on and so forth, which is the major responsibility of the Center at the VAMC in Miami. The second is on evaluation of treatment guidelines, editing of items that go into the VA Web site, and monitoring and supervision of re-



search, such as the industry-funded 26 center study of combination therapy and studies of new drugs such as pegylated interferon, which is from San Francisco.

So they are not designated as a Center of Excellence specifically for the treatment of hepatitis C. They are Centers of Excellence for the VA as a whole in areas of educational materials, counseling, guidelines, and clinical research. I dare say that the clinicians at Miami or at San Francisco would not hold themselves out to be members of a Center of Excellence greater than that in New York or in Minneapolis.

Mr. SHAYS. You heard witnesses who testified earlier who basically described I think some pretty alarming examples of how they wanted the service, they felt they were entitled to it, they were sick and were either being told they did not have a problem, or they had a problem but we couldn't treat you a particular way. You have been kind of silent to that. I would love for you to just talk a little more about what you heard and tell me what I should infer from that and what the committee should infer.

Dr. HOLOHAN. Well, I will speak for Central Office. There have been a number of times when such statements or claims have been made and I have always said to VSO representatives or in some cases VA employees that if you have an incident like that, you tell me. I have given my phone number and e-mail out at our national meetings. It is something I want to know about and it is something I am sure that Dr. Garthwaite wants to know about. It is difficult for me to understand why, assuming this is in fact accurate, that a VAMC would tell a patient known to be positive for hepatitis C that it is their practice not to do liver biopsies and not refer them. That does not make any sense.

Mr. SHAYS. It does not make any sense, but we had testimony that in fact was happening. So are you saying that it does not happen, or are you—

Dr. HOLOHAN. I am saying, chairman, that this is the first time this has been called to my attention.

Mr. SHAYS. We had testimony last year that there were cases where people were not being covered, and we cited three cases. Mr. Baker came back today and just said:

I have been asked to followup on the examples that I produced last year. Mr. Chairman, I am sorry to report that these veterans' lives have gotten dramatically worse. The veteran from Idaho was finally tested, but has not yet been allowed to receive treatment in VISN 19, in fact, he has been told that despite evidence of fibrosis of the liver, his enzyme levels are not elevated enough to consider him for treatment. As for the veteran from Montanan, the VA has "done a fine job"—he was never treated for his hepatitis C and in November of last year he succumbed to complications from a liver transplant due to Hep-C. I attended his funeral. In the case of my personal friend from New Jersey that served with the 173rd Airborne, he is now number 7 on the liver transplant waiting list. Even though we personally hand-delivered his case to Dr. Garthwaite, NO, I repeat NO action has been taken. The VA continues to maintain that this recipient of the Bronze Star for Valor cannot show a nexus between his service and his hepatitis C infection because his duty assignment was not "medic."

Dr. HOLOHAN. I can respond to at least two of those, not the patient who has died. The patient in Idaho, according to information I have received from VA people, refused to allow his name or social security number to be made known to the VA, so we cannot track him. The patient in New Jersey, I have, and I can forward it to

you, a letter from Mr. Eppley to the regional office in New Jersey saying that the evidence they had, despite the fact that the diagnosis of hepatitis C was made in the civilian sector, established a nexus because of his service in Vietnam and that the regional office should consider his claim as well-grounded.

Mr. SHAYS. And what is the status of that?

Dr. HOLOHAN. All I can tell you is that I received yesterday a copy of the letter from Mr. Eppley to the regional office telling them they should consider his claim for a service-connection as well-grounded.

Mr. SHAYS. But that is yesterday.

Dr. HOLOHAN. I am not sure what you mean.

Mr. SHAYS. This was an example at a hearing we had many, many, many, many months ago.

Dr. HOLOHAN. We were unable to get names and social security numbers of the people cited last year until very recently.

Mr. SHAYS. When Mr. Bryant spoke, he said: "In early 1999 I went to an appointment at the Spokane VAMC. I told the VA doctor of my concerns about my hepatitis C and the health of my liver. I asked for a liver biopsy and a viral load test, as those were the VA's own procedures for treatment of HCV. I was shocked and surprised by his answers: One, this hospital has a policy of not doing liver biopsies. Two, in looking at your past LFT tests, you do not meet the protocols for interferon treatment as they are below twice normal. Three, I will order a viral load test and we will discuss it at your next appointment in 3 months."

What should I infer from that?

Dr. HOLOHAN. That is wrong. That is inadequate medical treatment.

Mr. SHAYS. Right.

Dr. HO. Mr. Chairman, if I might just add something. I think there is a lot of frustration on the part of veterans who are informed by the Internet and by support groups and who have certain information and who perceive that there is a lack of education on the part of their health care professional. It is an ongoing issue about education of our health care professionals. You optimally need a liver specialist who has been able to keep up to date to really give the appropriate recommendations. There just are not that many in the VA medical centers. In the entire State of Minnesota, there are maybe a couple hundred gastroenterologist, but of those couple hundred there is maybe 20 who really have kept up to date and who are treating the majority of liver, and hepatitis C patients in the entire State. So you can see that confusion about interpretation of current data might happen in a clinical setting.

Mr. SHAYS. Miss French used the statistic of 10 percent of our veterans, Dr. Iber, having hepatitis C. That seemed to me a bit inflated. Would that be a statistic you would agree with?

Dr. IBER. I think it is pretty close to that. I feel that it is 8 percent, but that is not recognizing that the two coasts of America have a much higher percentage. So I think 10 percent may well be an accurate figure.

Mr. SHAYS. Dr. Brau, in your facility, what are you finding as the statistic?

Dr. BRAU. We take the statistics from the survey which was done really on an unselected population in March 1999, which is not the same as if you look at the antibody tests of those who are tested because of risk factor or liver disease. And by that statistic, our network has 13 percent, and our facility in excess of 14 percent.

But to catch up on what was mentioned earlier, I believe every VA medical center should have a dedicated center for hepatitis C. I am particularly encouraged by the growing number of my infectious disease colleagues who are interested in going to this field and get themselves educated and become experts.

Mr. SHAYS. Given the number of 14 percent, somewhere in that range, just use the number 10 percent, we are saying that 10 percent of particularly our Vietnam veterans—

Dr. IBER. All veterans.

Mr. SHAYS. All veterans.

Dr. IBER. Higher in Vietnam.

Mr. SHAYS. All veterans, not 1 percent, not 2 percent, 10 percent have hepatitis C and we know it to be a silent killer. It would strike me that this is a gigantic percentage and one which, Dr. Ho, your comment, though truthful, is somewhat alarming that we do not have the expertise in our facilities. Hence, Dr. Holohan, we have this problem. You have restraints based on dollars. But I always believed if I were in your shoes or anyone else's shoes in the administration, I would lay it on the line to Congress and then say Congress it is in your lap. But it is not presented that way. I would think VA would say we need this amount to deal with this problem, to deal with the protocols that we have, and anything less than that will mean that you will get substandard care. And then it is on Mr. Snyder's table, my table, and Mr. Souder's table. But I do not think we are getting that yet. So then it goes back on the VA.

We get a lot of stories like this that you say are unacceptable. But I do not think these are exceptions, I think they are more the rule based on, as you have pointed out, Dr. Ho, that we just do not have the expertise. And do we all agree that if they are not treated they become ill and die. Is there anyone who disagrees with that?

Dr. BRAU. Mr. Chairman, not everybody who tests positive for the antibody actually has the chronic viral illness. If you count the false-positive rates and those who cleared the virus through their own immune system, about two-thirds of those who have antibody test positive have the virus. And of those who have chronic virus in their blood and in their liver, some patients do not progress that far. So we see patients who have been infected 40, 50 years and on biopsy have minimal liver disease. So for them, they will probably not be killed by the virus. But others progress much faster and that is why we need to do a specialty evaluation including liver biopsies to see who is most urgently in need of treatment.

Mr. SHAYS. That should be able to take place at any VA hospital?

Dr. BRAU. Yes.

Dr. IBER. Agree.

Mr. SHAYS. And it does not right now, correct?

Dr. HOLOHAN. That appears to be the case.

Mr. SHAYS. Mr. Souder is here to Chair, but I will yield the time now to Mr. Snyder and then he can claim time.

Thank you very much, gentlemen.

Mr. SNYDER. Thank you very much, Mr. Chairman. I just have three or four more questions.

Dr. Ho, I wanted to ask you a bit of an unrelated question. You talked about the combat blood exposure in your comments. You had the fairly dramatic example of a piece of a leg bone being implanted in one of your patients. I assume that we are talking about exposure to kind of the large amounts of blood that can occur in combat situations, not just the fact of being under fire, but the subsequent people that would treat, potentially the folks that load them into helicopters, the folks that are at the field medical facilities. Is that correct.

Dr. HO. I have one patient who was an ambulance driver actually at a base here in the States during the Vietnam war, and at that time it was not common practice to use plastic gloves. If someone was bloody, you just grabbed them and hauled them in. And as far as we know, that is the only risk factor that particular patient had for hepatitis C. So it involves that, the blood transfusions, and then the actual combat injuries and blood exposures that are risk factors. These are significant risk factors, as shown by research done by Dr. Wright's group in San Francisco, and of course unique to this patient population.

Mr. SNYDER. Dr. Brau, you mentioned earlier that you expect waiting times will become longer, which is kind of an ominous sign for Members of Congress who hear about waiting times, and of course for the veterans who want to be treated. Do you agree that if you have longer waiting times that is kind of a symptom of what Dr. Holohan and Dr. Iber describe as an overwhelmed system. Is that how you would describe where you are at today?

Dr. BRAU. That is correct. And that sort of stresses the fact that the support for the treatment includes not just the drug cost and the laboratory cost, but also staffing which needs to be added to have really a comprehensive multidisciplinary team to take care of the problem. One thing that we have found also is the longer the waiting time, the higher the drop-out rate. So patients get scheduled but then they do not show up. We will call them to reschedule them. But we would like to have the waiting time as short as possible.

Mr. SNYDER. You mentioned infectious disease specialists, not just GI doctors as becoming potential providers of treatment. Are you within your system looking at some creative ways, taking some general internists, for example, already within the system and giving them additional training, or is it going to have to be a gastroenterologist that is primarily the specialist that does the ongoing care?

Dr. BRAU. I think we should look first at the specialists who are most involved in this disease. This is an infectious disease that does involve the liver. And while traditionally the studies on the non-A, non-B hepatitis, which was not known to be virally caused, was done by gastroenterology, more infectious disease experts are getting into the field and they bring in all of the experience with the other big viral disease, HIV. So I think it lends itself to a collaboration. There might be the occasional general internist who has a lot of dedication to the disease and is willing to educate herself

or himself to the illness, but I think we do have a number of infectious disease and gastroenterology, hepatology specialists who together can put a comprehensive treatment program in place.

Mr. SNYDER. HIV has been mentioned several times I guess because you use comprehensive teams. Are there other diagnoses within the VA that also have special care teams or comprehensive teams? What are some examples of that, Dr. Iber, you are nodding your head.

Dr. IBER. Chemotherapy I think uses a superb specialty team, albeit usually a little shorter than hepatitis C. But I think actually we incorporate the chemotherapy team and our patients get great care in fact when the chemotherapy team of nurses and consultants is responsible for them.

Mr. SNYDER. Do we have a shortage, Dr. Holohan, of oncologists in the VA system also?

Dr. HOLOHAN. Yes, sir, we do.

Mr. SNYDER. Would you describe our treatment of cancer within the VA system as "the harsh reality, it is overwhelmed by our system," or not?

Dr. HOLOHAN. No. In fact, I think we have adapted better in the oncologic arena than we have in hepatitis C. I think part of that is simply a function of time and learning how to save energy and resources while getting the job done.

Mr. SNYDER. The last question I want to ask you, Dr. Holohan, I assume that the chairman will want to do followup or maybe the VA will want to do hearings in the future, 6 months from now, will the harsh reality of our veterans' system for care of hepatitis C be that we are overwhelmed?

Dr. HOLOHAN. I think trying to respond to that prediction is the surest way to appear a fool in 6 months. I hope not, but I am not sure.

Mr. SNYDER. Do you have a specific action plan in mind that is going to change that reality over the next 6 months?

Dr. HOLOHAN. Well, some we have already talked about. I think the clinical assessment reminder system has dramatically improved the evaluation and screening. I think that the additional funds released this fiscal year by the Under Secretary will help, and I think the adjustments, whatever they may be, in fiscal year 2000 about increasing funding for hepatitis C based on the workload and predictions as to cost will change the budgetary circumstances significantly. Now in terms of being able to go out and dramatically increase the number of gastroenterologists or infectious disease experts, I am not quite so sanguine because that is a perennial problem for VA or any salaried medical care system.

Mr. SNYDER. Dr. Iber, do you have a comment?

Dr. IBER. Yes. I think that the VA has great success particularly with this computerized recognition of screening and the need for it in identifying more patients. My concern is what do we do with them then. I think that they are very slow. The principal use of moneys has been to pay for the drugs which are very expensive, but I think availability of drugs has not been a problem in my experience for at least 2 years. We have made them available, we get what we need in any quantity we need them. But the personnel assigned with priority to supervise the safe administration of these

drugs is the big ingredient that is lacking, at least in the center that I am familiar with, and as I talk to colleagues in the greater Chicago area, that is a pretty uniform problem in our five VA hospitals there, we cannot keep up with the load.

Mr. SNYDER. My last question for each of you is just a general question. Knowing you as somebody who has practiced medicine for 20 years and have been around academicians, you are a pretty independent minded group. Is there anything, Dr. Brau, that you would like to comment on today that you think we ought to know about?

Dr. BRAU. I think the effort is ongoing in the VA system, in some centers more than in others, but everybody is going in the right direction. I think if we get the right support, we can maintain a very high level for the treatment of our veterans with hepatitis C. The issue of personnel that is dedicated to this does need to be addressed in the support system.

Mr. SNYDER. Dr. Ho, any last comments?

Dr. HO. I think the concerns expressed today are important and I know the commitment of the administration of VA is very much there and I think, in general, ahead of the ball game. The big issue now is finding these patients with hepatitis C and educating them. I think it boils down to each VA medical center needs at least one or two full-time personnel dedicated to hepatitis C. We need to find the patients with hepatitis C because in a year, a year and a-half, our treatment is going to change, and it is going to be much better, I believe, and then we are going to need to start treating these people. We have a lot of people just waiting for that.

Mr. SNYDER. Dr. Iber, any final comments?

Dr. IBER. I have some concern that the VA is putting a lot of thrust on developing their own materials, their own guidelines as though the veteran with hepatitis C is completely a different species of cat from the civilian one. I think that is totally incorrect. There has been a tremendous amount of work done, there are wonderful educational materials out there on the civilian side that are reproduced by industry. I wonder if the VA, rather than develop their own through a Center of Excellence designed to this and creating what has been in my experience third-rate and mediocre pamphlets and educational materials compared to what is already out there, that they might be well off just to incorporate existing ones into the thing and get on the problem of using their resources for the task at hand of treating the veterans in the various facilities.

Dr. HOLOHAN. Let me interject by saying we do that, we use materials produced by Hepatitis International and the American Liver Foundation, not intending to reinvent the wheel.

Mr. SNYDER. Dr. Holohan, do you have any last comments?

Dr. HOLOHAN. Only one, and that is there was a statement made in an earlier panel that VA treats those patients who benefit the least, that the people who could benefit the most are not treated by VA. I would like to see evidence of that. I think my two colleagues who are treating patients both in the midwest and in New York would probably not agree that they are personally treating patients that benefit the least.

Mr. SNYDER. Thank you all for your time today. Let me just say in closing, Congress is your ally in this business. This is a whole new entity. You all have been perhaps leaders in the world in dealing with this disease and we want to help you with it. I know Mr. Shays feels that way, I know the Veterans Committee feels that way. But I hope you will feel free to let us know when there are things that we need to be doing. I appreciate your time today. Thank you all.

Mr. SOUDER [PRESIDING]. Dr. Ho, I wanted to followup on a comment that I heard you say a little bit ago, which is that in all of Minnesota you only had was it 20 people or 50 people who could effectively be current on this disease.

Dr. HO. It is a rough estimate. The people who are familiar with hepatitis C are ones who go to the annual meetings and keep up. It is a constantly changing and evolving area. Again, to my knowledge, there is a small minority of gastroenterologists who are doing the large majority of the care of hepatitis C patients in the State of Minnesota.

Mr. SOUDER. Are you saying that there is a shortage in the general population as well as in the VA of people who—

Dr. HO. The State of Minnesota currently has a shortage of gastroenterologists in the entire State. Every single private group, to my knowledge, is looking to hire more gastroenterologists and are having some difficulty doing that.

Mr. SOUDER. Does that tend to be true nationally, do you know, Dr. Holohan?

Dr. HOLOHAN. Yes. In general, that is the case. I do not want to get on a philosophical course about the push toward primary care and what we are seeing now as new technology develops, the shortage of interventional radiologists, medical oncologists, gastroenterologists, cardiologists, but in fact that is a common thread. That is one of the reasons why the VA is one of the few agencies that still will issue waivers for J-1 visas for medical specialists.

Mr. SOUDER. It is my understanding that you have asked for \$20 million in the national reserve fund to supplement funding for hepatitis C testing and treatment but that you have only spent \$39.2 out of the \$190 million that we allocated in last year's budget. Could you explain why that money was not spent?

Dr. HOLOHAN. Since I have gotten your snap from center, I will now punt to the Chief Financial Officer.

Mr. NORRIS. First of all, let me say that I am a Vietnam veteran and am one of the medevac pilots that Miss French referred to from that war. In fact, due to the timing, I may very possibly have been the medevac pilot that evacuated Mr. Lesinski when he was wounded. So I go back a long way with concern for these veterans and I do not think that feeling is unique within the VA; I think that feeling permeates the organization.

We have concerns about that because we do have \$195 million in the budget this year for hepatitis C. As best we can tell, as you stated, we spent about \$39 million through the first half of the year, and we currently expect to spend about \$100 million of that by the end of the year. The money is out there. We are perplexed as to why it is not being spent. I suspect that part of it is for the reasons that have been stated in terms of access, availability of

providers to screen, to provide the treatment, and to get the patients in.

We do want to provide more visibility for that. So we have sent out \$20 million tied specifically to those costs that have been experienced in the system so far this year. We hope before the beginning of the fiscal year to change our VERA allocation model so that it will actually highlight that we have money tied to hepatitis C for complex care patients and get that out so that everybody will be aware that the money is available. We have \$340 million in the budget next year for hepatitis C. But we do have concerns about hepatitis C spending and there is an effort to make sure that we are doing all we can do from a financial standpoint to make the resources available.

Mr. SOUDER. So what I understood you to say is you do not know why it is not being spent. And how are you trying to find out?

Mr. NORRIS. One of the problems we have had is actually tracking the expenditures. So because we do not have data, as Dr. Holohan mentioned earlier with tracking patients, we do not have data specifically designed to track and record hepatitis C costs. So it is possible that we are spending more than that and we just cannot identify it. We have set up a pretty elaborate system to identify those patients and to identify the cost associated with them, made some assumptions about cost associated with those patients for screening and testing of patients who turn out to be negative, because there is a cost to that.

So we are doing everything we can to determine what we are spending, and the fact that we are not spending everything that we should be is a concern. But, as I said, I suspect it is because of the lack of ability to get this up and running. It took us a few years to get the AIDS program up to the status that it is now, and we do that pretty well I think. So I think we want to pattern what we are doing here with hepatitis C after that and employ some of the lessons learned there and hopefully improve our tracking hepatitis C costs. But it does take a little time to get that going.

Mr. SOUDER. My understanding is it has taken almost 2 years to try to get a data set together that you can compare. Because you are just telling me that part of your problem is you do not have the data, and my understanding is it has been about 2 years in trying to develop this data. Why is it taking so long to figure out what you need to compare to? Did this suddenly just drop in your lap?

Mr. NORRIS. No. The point I was trying to make is that we are concerned about the lack of the spending. And to date, the amount that we have identified as spending on hepatitis C does not approach the estimates for our projections based on various assumptions that we made that may be incorrect. But it at least raises the issue. And so we have scoured the data bases, we have actually established now this registry, that Dr. Holohan mentioned, which we are bumping these various data bases against to make sure we are accounting for every patient. I am simply saying that we are looking to see if there is something we are missing. We are not sure that we are, but if there is something, we want to know about it.

Mr. SOUDER. I would yield to Mr. Snyder.

Mr. SNYDER. The staff has put in my hand a copy of the transcript from the hearing that Mr. Shays conducted in June 1999.



Mr. Brownstein, who was the president of the American Liver Foundation, if I just might read a paragraph of his testimony looking prospectively at this issue of how to spend the money. He said: "First of all, the \$250 million of treatment that has been committed will not happen. It will not occur unless the infrastructure is developed. You cannot just have money for treatment without having the mechanisms to deliver the care. So the worst thing that could possibly happen is you reconvene this body next year and find out that only \$30 million, \$50 million, or \$75 million was spent in the year 2000. That would indeed be a tragedy because that would not signify there isn't a need, it would signify that we have not effectively translated that need into an effective demand that can be responded to." Mr. Brownstein gets some points for prediction, doesn't he. Thank you, Mr. Chairman.

Mr. SOUDER. The concern I have is not that we should not be spending the money, and that in fact sometimes does happen when the money doesn't get spent that people will question it, but in this case your request is even going up. A problem that I would have, as somebody who is not an expert in this at all, is if the general population is 1.8 to 2 percent, veterans are looking at 8 to 10 percent, we have heard here this morning that this did not suddenly occur, the Vietnam war was not over last year, and what I am hearing is that you are trying to figure out, trying to sort that through, and trying to rectify data bases. It may be that there are not sufficient people even to treat it if you find that. But I have a concern as to why this took so long.

Second, the funds are there. We need to have clear explanations as we are moving through, and we will have budget questions, but we also need to make sure our veterans are covered and that with all due diligence we find that so. And if it is an infrastructure problem that we do not have enough people in the specialty area, that is identified to Congress and that becomes a focus. If it is a problem that there is not enough outreach to the veterans, then that becomes a focus. But there needs to be some clarity as we move through this and your execution of this program.

I want to thank each of you for being here, as well as those veterans who were willing to speak out on the first panel, as well as Miss America.

I think one thing that Chairman Shays has proven, both in this committee and over in the human services side and the Medicare where I worked with him for a number of years, is that he is aggressive in followup and in continuing interest, whether it has been the Persian Gulf Syndrome question, whether it has been in anthrax vaccinations, or hepatitis C. He will be persistent, he will continue to monitor, and he will work for the legislative and funding needs that we need. And while not all the members may be here today, we have aggressively backed him up in that because we know the thoroughness that the staff pursues in these issues.

So we would appreciate it if you will stay in touch with us and be aggressive with us. Nobody deserves our care more than those who sacrificed for our country and often they are in the back seat

in how they get their care. So we want to be more aggressive in making sure that they are covered.

With that, this subcommittee now stands adjourned.

[Whereupon, at 1:25 p.m., the subcommittee was adjourned.]

[Additional information submitted for the hearing record follows:]



NATIONAL HONORARY  
SPOKESPERSON  
MOM JACO

BOARD OF DIRECTORS

Chair  
JOHN M. VIERLING, MD  
Cedars-Sinai Medical Center  
UCLA School of Medicine  
Los Angeles, California

President and  
Chief Executive Officer  
ALAN P. BROWNSTEIN  
New York, New York

Vice Chair

IRVIN M. ARIAS, MD  
Tufts University  
Boston, Massachusetts

BRUCE R. BACON, MD  
Saint Louis University  
School of Medicine  
St. Louis, Missouri

LOUISE M. JACOBI  
Kaiser Permanente  
Fresno Medical Center  
Fresno, California

ROY H. LOPATA, PhD  
City of Newark, Delaware  
Newark, Delaware

JOHN R. RYAN  
Cummings, Georgia

Secretary  
JOHN W. PORTER, JR.  
Albion, Pennsylvania  
Pittsburgh, Pennsylvania

Treasurer  
JEFFREY F. JORDAN  
Frost & Nowakowski, LLP  
Houston, Texas

Assistant Treasurer  
ANGELA L. GERTZ, Esq.  
Denver, Illinois & Illinois  
Chicago, Illinois

Medical Director  
ALAN M. G. BUCKLE, MD  
Saint Louis University  
School of Medicine  
St. Louis, Missouri

Chairman  
DAVID AGARWAL, MD  
University of North Carolina  
Chapel Hill, North Carolina

OTHER ADVISERS  
Congressional Hepatitis Caucus  
Washington, DC

SHARON E. BARRETT, MS  
Health Resources &  
Research Administration  
Baltimore, Maryland

EDWARD BLAIR  
Pharmaceuticals, LLC  
New York, New York

JOHN M. BLOCH, RN  
Hospital of Fundamentals  
Drexelton, Pennsylvania

WILLIAM RUTHERFORD, JR.  
Compass Bank  
Birmingham, Alabama

JOHN T. FARRAR, MD  
Hennepin County  
Minneapolis, Minnesota

EUGENE FERGUSON, PhD  
Aer Aerobics, Michigan

BRIAN GORDON  
Alco Chemical Resources  
Coe, Maine, Nevada

CHARLES G. HOWELL, MD  
University of Maryland  
Baltimore, Maryland

JOSEPH C. ISAACS  
American Hepatitis Association  
Chicago, Illinois

SUDAN JEROME  
Andover, Massachusetts

WILLIAM LAUREN LUCAS  
Washington, DC

WILLIAM T. LUCHE  
Lyons and Company  
Washington, DC

PETER MACQUE  
State Department  
Boston, Massachusetts

ESTERAN MEZKY, MD  
Johns Hopkins University  
School of Medicine  
Baltimore, Maryland

MARK A. ROTHSTEIN, MD  
University of Houston  
San Antonio, Texas

RONALD J. SCHOL, MD  
Children's Hospital  
New York, Colorado

JOHN W. TEFERMAN, MD  
New York University Hospital  
New York, New York

JOYCE WELLS  
Fairfield, Connecticut

STATEMENT  
OF  
THE AMERICAN LIVER FOUNDATION

PROVIDED  
TO  
THE UNITED STATES HOUSE OF REPRESENTATIVES  
COMMITTEE ON GOVERNMENT REFORM

SUBCOMMITTEE ON NATIONAL SECURITY,  
VETERANS AFFAIRS  
AND  
INTERNATIONAL RELATIONS

BY

ALAN P. BROWNSTEIN, MPH  
AMERICAN LIVER FOUNDATION  
PRESIDENT AND CHIEF EXECUTIVE OFFICER

JULY 12, 2000

### **The American Liver Foundation**

Mr. Chairman and members of the Subcommittee, my name is Alan P. Brownstein and I am the President and Chief Executive Officer of the American Liver Foundation (ALF). Thank you for giving our organization the opportunity to submit testimony regarding the vulnerability and risk of veterans to hepatitis C infection and the response of the Department of Veterans Affairs.

ALF is a national voluntary health organization dedicated to the prevention, treatment and cure of hepatitis and other liver and gallbladder diseases through research and education. ALF has 30 Chapters nationwide and provides information to more than 300,000 patients and families. More than 70,000 physicians and scientists, including primary care practitioners and liver specialists, also receive information from ALF.

The ALF Board of Directors is composed of scientists, clinicians, patients and others who are directly affected by liver disease. Every month, ALF receives approximately 15,000 calls requesting information about hepatitis and other liver diseases. Over 90% of those calls are about hepatitis.

ALF was founded 24 years ago by the American Association for the Study of Liver Diseases. In recent years, ALF has provided more than nine million dollars to support hepatitis/liver disease research and more than ten million dollars to promote public awareness about hepatitis.

### **Applauding the Committee's Leadership**

On behalf of the American Liver Foundation, we applaud the continued leadership of this Committee to bring appropriate focus and attention to hepatitis C and liver disease problems that exist among the veteran population. With your leadership, we believe that much progress has been made. We also applaud the efforts of the Department of Veterans Affairs as we believe both nationally and at the VISN's across the country a commitment to this problem is evident. We would note, however, that the Department of Veterans Affairs has consistently under-spent its budget that has been made available by Congress. For example, in FY 1999 \$46 million was made available for hepatitis C funding, but only \$27 million was spent. In FY 2000, \$195 million has been made available, but only \$100 million has been spent. The House Appropriations Committee has recommended and the full House has supported spending \$340 million in FY 2001.

We applaud your leadership, but believe much remains to be done. We would encourage the Committee to focus its attention to the continued under-spending by the Department of Veteran's Affairs on the hepatitis C crisis that exists among the veteran population.

### **ALF's Veterans Hepatitis C Liver Disease Council**

Since testifying before this Subcommittee last year, ALF has formed the Veteran Hepatitis C Liver Disease Council to address the issue of hepatitis C and liver disease in the Veteran population. This council brings together representation from Veteran Service Organizations, Veteran Health Administration officials, the nation's leading medical authorities on hepatitis C, and ALF leadership to identify and implement the most expeditious means to increase the rate of

testing and treatment for hepatitis C for at risk veterans. This Council stands unified in its firm commitment to help meet the needs of veterans affected by the hepatitis C virus.

The Council has identified four major goals of this campaign:

- Raise awareness of hepatitis C infection risk factors/prevalence among veterans
- Motivate veterans who may be infected with hepatitis C virus to seek testing and as appropriate, seek treatment
- Provide credible, up-to-date hepatitis C information and education to at-risk veterans and those receiving treatment
- To achieve the above goals through education and advocacy.

Following the Council's first inaugural meeting on June 15, 2000, two major campaigns are currently underway to help raise awareness of hepatitis infection risk factors. First, during the celebration of Independence Day last week (July 3-9), the Council's first initiative helped over 1,500 at-risk veterans get tested free of charge for hepatitis C through a nationwide promotion using an FDA approved home testing and counseling service (manufactured by Home Access Health Corporation).

Secondly, ALF has developed a veteran hepatitis C information brochure that is to be accompanied with a letter signed by the VA's Deputy Undersecretary for Health, Dr. Thomas Garthwaite and sent out to the 3.6 million veterans that use the VA health system. This letter with the ALF brochure is being printed and will be mailed to veterans in the near future.

**The Prevalence and Impact of Hepatitis C in the United States and Among Veterans**  
Hepatitis C, designated by the CDC, as an "emerging infectious disease" is one of the most serious public health problems that the United States will face as we enter the 21<sup>st</sup> century:

- Four million Americans have been infected with hepatitis C and most don't know it.
- Ten thousand people die every year from Hepatitis C, and this amount is projected to triple in the next 10-15 years.
- Hepatitis C is the leading cause of liver transplantation.

Hepatitis C is a democratic disease that affects everyone – all races, men, women and children. It mirrors mainstream America...doctors, lawyers, teachers and even soccer moms, not just those who received blood transfusions prior to 1992 and illegal injection drug users. However, it is important to recognize that some populations are more vulnerable to chronic hepatitis C than others. For example:

- 1.8% Overall U.S. population
- **8 - 10% Veterans**
- 3.5% Overall population between the ages of 35-55
- 1.5% White
- 3.2 % African-American
- 2.1% Mexican-American.

Clearly, hepatitis C is a well-documented major health challenge for U.S. Because hepatitis C is a “quiet” virus, the vast majority of veterans with hepatitis C do not have symptoms, and thus, are unaware that they are affected. This combined with the prevalence of hepatitis C, and the fact that it is a serious, potentially life-threatening condition, underscores the importance of identifying those veterans who are infected. And further, new studies show that treatment succeeds in about 40% of patients who are suited for treatment. And even for those who do not respond to treatment, it is important that they become aware, because there are interventions that can significantly slow down the progression of hepatitis C damage to the liver – for example, by abstaining from drinking alcohol, and making sure they are immunized to protect them from hepatitis A and B.

#### **Veterans Health Administration Response**

As stated in the Department’s budget documents, hepatitis C has particular importance because of its prevalence in the VA’s service population. The Administration’s Fiscal Year (FY) 2001 budget proposal requests \$340 million to support efforts to test and treat veterans with Hepatitis C. This is \$145 million more than the \$195 million made available in FY 2000 for this purpose. As noted earlier, while the budget requests and expenditure levels have increased, there has been a significant spending shortfall below amounts made available.

To address needs of hepatitis C positive veterans, VA designated medical centers in Miami, Florida and San Francisco, California as “Centers of Excellence” to serve as research and education lynchpins in VA’s 5-point strategic initiative to respond to hepatitis C. The 5-point strategic initiative includes: 1) patient education; 2) health care provider education; 3) epidemiologic assessment; 4) treatment; and 5) research.

The Centers of Excellence have also developed risk factor and counseling recommendations for all VHAs, as well as treatment guidelines for the care of veterans with hepatitis C. These treatment guidelines will be updated periodically, and as there is a greater experience of clinical care, they can be broadened to be more inclusive. Management guidelines, such as the need of vaccination against hepatitis A and B, have also been distributed throughout the VHA system.

In collaboration with the Centers of Excellence, ALF has developed ten fact sheets on hepatitis and liver disease for veterans. These educational materials have been widely distributed throughout the VA system.

Significant progress has been made, but more needs to be done. The recommendations of the ALF follow.

#### **ALF RECOMMENDATIONS:**

##### **Challenges for the VA Hepatitis C Testing, Diagnosis & Treatment Program**

While it is clear that the commitment and significant budgeted support is in place to launch a public health campaign directed at hepatitis C among U.S. veterans, many challenges lie ahead. If these challenges are not addressed, it will not be possible to spend anywhere near the \$340 million that has been budgeted. Some of the challenges facing this major public health undertaking are identified below along with the identification of some public and private sector partnership opportunities.

**Challenge #1 - Infrastructure Development**

In order to meet the increased demand for hepatitis C services, additional medical, psychological and managerial personnel will be needed at the VA's VISN/VAMC Network.

- **Public Sector Efforts Needed:** Additional funding support needs to be identified and dedicated to support the additional personnel that will be needed over the next 4-6 years to meet the demand for hepatitis C treatment.
- **Private Sector Efforts Needed:** Methods for training primary care personnel to manage hepatitis C patients in consultation with specialists need to be explored. One such model being developed at ALF involves a program to increase the "Quantity and Quality of Health Care Services Provided in the Management of Chronic Hepatitis C Through the Expanded Use of Nurse Personnel." This plan has the potential for developing a training module coupled with a recruitment strategy to bolster the supply of hepatitis C certified nursing personnel available for employment within the VHA Network or through some external contract mechanism should the expansion of FTEs not be feasible. Developing and implementing this recruitment and training initiative could be done for \$1.5 million over two years.

**Challenge #2 – Health Provider Education**

- **Public Sector Efforts Needed:** The designation of "VA Hepatitis C Centers of Excellence" and the National Hepatitis C Symposium (June 3-4, 1999) are excellent examples of how VHA is seeking to educate its personnel. It appears that VHA is seeking to make sure information on hepatitis C is communicated to its health personnel on an ongoing basis.
- **Private Sector Efforts Needed:** ALF has been running an ad "Combating a Crisis" in numerous primary care journals. It is also using this ad in conjunction with mailings to primary care physicians through health departments. This ad, which provides succinct information for primary care practitioners about hepatitis C, can be easily adapted to be specific for VA primary care practitioners. ALF would be pleased to do this in consultation with VA hepatitis C leadership and have it distributed throughout the VA system.

ALF is currently exploring ways in which it could assist in training primary care practitioners through its nationwide network of chapters and their medical leaders, many of whom are involved in their local VISN/VAMCs. There are numerous ways in which public and/or private resources can be used for this purpose.

**Challenge #3 – Veteran Education and Outreach**

Educational materials and outreach strategies must be employed to stimulate the vast reservoir of unmet needs among undiagnosed veterans with hepatitis C.

- **Public Sector Efforts Needed:** Ongoing communications between VHA and VSOs.  
Development of educational materials through the VA Hepatitis C Centers of Excellence.
- **Private Sector Efforts Needed:**

ALF is currently working with its chapters to develop these programs targeted to veterans:

- **Meet the Researchers** – ALF's educational series featuring leading liver specialists. Working with local VISN/VAMCs, ALF plans to hold up to 36 symposiums the first year throughout the U.S. focusing on issues specific to veterans. These half or full day conferences will be sponsored by both ALF's local chapters and National Office. The symposiums will provide veterans with access to current information on treatment and disease issues that might not otherwise be readily available.
- **Support Groups** - ALF chapters will be forming support groups targeted to veterans. Support groups provide a forum to share concerns about diagnosis and treatment, discuss coping issues and provide support from other veterans. These support groups also provide another opportunity for education as local health care providers are invited to participate by speaking at these meetings. Over the next year, ALF expects to form 30 support groups meeting monthly through local chapters. A health care professional will be hired to coordinate and facilitate each group.
- **Outreach** – ALF has developed cultural “blueprints” targeted to different racial and ethnic populations for hepatitis awareness. These efforts and materials need to be developed and implemented in culturally appropriate ways.

For all the challenges listed above, it is important that accountability mechanisms be established by the VA that include the following:

- performance measures for testing, diagnosis and treatment
- performance measures for outreach and education
- establishing a database to measure performance
- annual reporting of results.

The hepatitis C liver disease problem facing veterans is not a one-year campaign. Instead, it will require a long-term commitment from the public sector and the private sector. It will also require a comprehensive use of different medical, psychosocial, and economic supports if it is to be successful in the long term. The ALF Veterans Hepatitis C Liver Disease Council represents the long-term commitment and unification of government and advocacy groups to face this epidemic.

ALF stand ready to work in collaboration with the VA and other in any public and private models to accomplish these goals. Again, we thank you for your leadership on these important matters.